88-330

Supreme Court, U.S.
FILED
AUG 23 1988
JOSEPH F. SPANIOL, JR.
CLERK

No. 88-——

IN THE

Supreme Court of the United States

OCTOBER TERM, 1988

AMERICAN CYANAMID COMPANY,
Petitioner,

v.

TRACY ISABEL ABBOT,
Respondent.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT

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QUESTION PRESENTED

Does federal law preempt a state common law design defect claim with respect to the only type of pertussis (whooping cough) vaccine that the federal government (1) licenses as safe and effective for sale, (2) actively promotes for use, and (3) purchases in large quantities for public distribution, where the claim is that the manufacturer should have produced a different and allegedly safer type of vaccine which the federal government is presently unwilling to license as safe and effective and which therefore cannot be lawfully marketed?

RULE 28.1 STATEMENT

Petitioner American Cyanamid Company has no parent company. In light of the purposes of Supreme Court Rule 28.1, petitioner construes the terms "subsidiaries" and "affiliates" to mean those corporations whose shares are publicly traded and a majority of whose shares are owned by American Cyanamid Company. American Cyanamid Company owns a controlling interest in Applied Solar Energy Corporation, but otherwise has no subsidiaries or affiliates so defined.

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PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT

OPINIONS BELOW

The opinion of the court of appeals below is reported at 844 F.2d 1108 (4th Cir. 1988), and reprinted as Appendix A to this petition. The unreported opinion of the district court, No. 86-857-A (E.D. Va. March 9, 1987), is reprinted as Appendix B to this petition.

JURISDICTION

The court of appeals entered its decision on April 20, 1988. On May 25, 1988, the court of appeals denied a timely petition for rehearing and rejected a suggestion for rehearing *en banc*. *See* Appendix C at 25a. This Court has jurisdiction to review the judgment below by writ of certiorari. 28 U.S.C. § 1254(1) (1982).

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

This case involves Article VI, clause 2, of the United States Constitution, which provides that

> This Constitution, and the Laws of the United States which shall be made in Pursuance thereof

> . . . shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or laws of any State to the Contrary notwithstanding.

This case also involves the Public Health Service Act, 42 U.S.C. §§ 201-300, specifically 42 U.S.C. § 262 (1982) (Regulation of Biological Products), and 42 U.S.C.A. § 300aa (West Supp. 1988) (National Childhood Vaccine Injury Act of 1986), and 42 U.S.C. § 247b (1982 & Supp. 1988) (Immunization Grant Program).[1]

STATEMENT

Respondent Tracy Abbot suffers from neurological deficit and developmental delay. On July 30, 1986, she filed this action in the Eastern District of Virginia,[2] claiming that her condition resulted from her inoculation in August 1983, at the age of five months, with Tri-Immunol®, a diphtheria-tetanus-pertussis ("DTP") vaccine manufactured by Lederle Laboratories, a division of petitioner American Cyanamid Company. In her complaint, respondent set out separate counts for strict liability, negligence, and breach of implied warranties, and asked for ten million dollars in damages. Petitioner answered the complaint, denying any liability.

After the close of discovery, petitioner moved for summary judgment, asserting that the constitutional doctrine of preemption barred respondent's claims. In the course of the summary judgment proceedings, including two hearings, it became clear that respondent sought to proceed only on design defect and related failure to warn theories.[3]

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[1] The relevant portions of these statutes are set out in Appendices D, E and I respectively.

[2] Respondent invoked federal diversity jurisdiction pursuant to 28 U.S.C. § 1332.

[3] Respondent explicitly acknowledged that, in light of the facts adduced in discovery, she could offer no evidence that the Tri-

Respondent's design defect claim rested on the contention that petitioner should not have produced a "whole-cell" pertussis (whooping cough) vaccine but, instead, should have made a "non-whole-cell" pertussis vaccine. The whole-cell design, so-called because it includes whole killed cells of the pertussis bacteria, is the only design currently licensed as safe and effective by the Food and Drug Administration ("FDA") for use in the United States. The federal Centers for Disease Control ("CDC") actively promote the administration of the whole-cell vaccine to all young children. The CDC purchases, and distributes in federally supported programs, almost half of all the whole-cell vaccine administered in the United States.[4]

Respondent, however, contended that petitioner should have produced either an "acellular" vaccine or a "fractionated cell" vaccine.[5] These alternative, non-whole-cell vaccine designs are today the subject of ongoing research by the federal government, the private sector, and governments throughout the world, all of which the federal Department of Health and Human Services ("HHS") carefully monitors.[6] HHS has, in this very case, stated

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Immunol that she received was defectively manufactured or failed to comply with the requirements of the Food and Drug Administration. *See* Appendix F at 31a-33a, and Appendix G at 34a.

[4] *See infra* note 33. In addition to petitioner, one other company, Connaught Laboratories, Inc., currently produces the whole-cell pertussis vaccine, under FDA license, for distribution in the United States. State health laboratories in Michigan and Massachusetts also produce the whole-cell vaccine for use in their states.

[5] Respondent expressly repudiated any claim that petitioner could have produced a better whole-cell vaccine and knowingly limited her design defect case to the allegation that petitioner should have produced a non-whole-cell vaccine. *See* Appendix F at 31a-33a; Appendix G at 34a.

[6] HHS's interest in this matter was set out in the brief of the United States as *Amicus Curiae*, filed in the court of appeals. That brief sets out the views of HHS and its subordinate unit FDA on

its view that these alternatives "have not yet been adequately shown to be safe and effective for licensure in the United States." [7]

In both the district court and the court of appeals, the preemption issue turned on the interpretation and effect of three statutes, all codified as parts of the Public Health Service Act. Under the Virus, Serum, Toxin Act of 1902,[8] as subsequently amended, the FDA pervasively regulates the licensing, manufacture and testing of vaccines, including DTP vaccines.[9] Under the Immunization Grant Program,[10] which began as the Vaccination Assistance Act of 1962 ("1962 Act"),[11] the federal government actively promotes and finances the administration of the whole-cell pertussis vaccine. Under the National Childhood Vaccine Injury Act of 1986 ("1986 Act"),[12] Congress created a no-fault system of federal compensation for injuries caused by certain childhood vaccines (including the whole-cell pertussis vaccine) which Congress

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the whole-cell vaccine and the ongoing search for alternatives. Since it is the FDA that must ultimately decide whether to license alternative vaccines, and since it is HHS that bears responsibility for implementing national immunization policy (including CDC purchases and federal and federally assisted research on alternatives), their views on the feasibility of alternatives must be considered in ascertaining the importance of the whole-cell vaccine to accomplishment of the goals of the Public Health Service Act. Accordingly, their brief ("HHS *Amicus* Brief") is reprinted in full in Appendix H and is relied on in this petition as an authoritative summary of HHS's views.

[7] HHS *Amicus* Brief, Appendix H at 51a.

[8] Pub. L. No. 57-244, 32 Stat. 728 (1902).

[9] In 1944 Congress consolidated the Virus, Serum, Toxin Act into the Public Health Service Act ("PHSA"), 42 U.S.C. §§ 201-300. *See* 42 U.S.C. § 262.

[10] *See* 42 U.S.C. § 247b.

[11] Pub. L. No. 87-868, 76 Stat. 1155 (1962).

[12] 42 U.S.C.A. § 300aa (West Supp. 1988).

deemed to have public health benefits that materially outweighed the injuries caused to a relatively small number of those receiving the vaccine. The 1986 Act allows claimants to reject an award of federal compensation in favor of a state law tort action, but partially preempts state tort law by allowing several federal defenses, including one for unavoidable side effects of a properly prepared vaccine accompanied by proper directions and warnings—a defense that would appear to bar the type of design defect claim made in the instant case.[13] The 1986 Act, however, applies only to vaccines administered after October 1, 1988,[14] and does not apply as such to the instant case.

The district court held that the above provisions of the Public Health Service Act (excluding the 1986 Act) preempt respondent's design defect claim under state tort law. The Court of Appeals reversed. Two judges (Murnaghan and Sprouse, JJ.) held that federal law preceding the 1986 Act did not preempt such claims. Although these judges "assume[d] [that] the 1986 Act is of no relevance in construing the preemptive intent of earlier federal legislation," they relied on the 1986 Act to show that "earlier legislation was of no preemptive effect." [15] The third judge (Wilkins, J.) held that federal law preceding the 1986 Act "appeared to preempt any state action alleging defective design of the DTP vaccine," [16] but that the 1986 Act showed that in previous legislation Congress intended no more than the limited preemption set forth in the 1986 Act.

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[13] This defense essentially adopts the rule of the American Law Institute's Restatement (Second) of Torts § 402A, comment k, which is followed by some but not all state courts. See *infra* note 50.

[14] *See* 42 U.S.C.A. § 300aa-1 note.

[15] 844 F.2d at 1113, Appendix A at 7a.

[16] 844 F.2d at 1116, Appendix A at 8a.

REASONS FOR GRANTING THE WRIT

I. THE COURT SHOULD GRANT CERTIORARI BECAUSE THE FEDERAL GOVERNMENT'S ABILITY TO CONTINUE TO EFFECTUATE A CONGRESSIONALLY MANDATED PUBLIC HEALTH POLICY IN THE FACE OF SPECULATIVE STATE LAW DESIGN DEFECT CLAIMS PRESENTS A COMPLEX AND URGENT QUESTION OF FEDERAL LAW

This case presents the important question of whether federal law applicable to vaccinations occurring before October 1, 1988, should be held to preempt respondent's design defect claim. Federal law preempts any state law that tends to frustrate "the accomplishment and execution of the full purposes and objectives of Congress." *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941). The preemptive effect of federal law extends to state common law, including state tort law, as fully as to state legislative action, since "[t]he obligation to pay compensation can be, indeed is designed to be, a potent method of governing conduct and controlling policy." *San Diego Bldg. Trades Council v. Garmon*, 359 U.S. 236, 246-47 (1959); *see also International Paper Co. v. Ouellette*, 479 U.S. 481, 107 S. Ct. 805, 815 n.19 (1987) (federal law preempts state law "regardless of whether the purpose of the [state] relief was compensatory or regulatory").

While there are many kinds of valid and sustainable state law tort claims that could arise out of vaccine-related injuries, there is one narrow class of claims that stands as a major obstacle to achieving federal objectives. Design defect claims that would impose liability for producing a whole-cell pertussis vaccine, rather than an unproven, unlicensed alternative that cannot lawfully be marketed, threaten to leave the nation without any licensed pertussis vaccine. Such a result would frustrate a federal public health policy that targets the pertussis

disease for maximum nationwide immunization with the whole-cell vaccine, the only vaccine than can lawfully be made and sold.

A. The Decision Below Would Severely and Unfairly Penalize the Manufacturers Who Made the Government's Pertussis Vaccination Program Feasible and Successful by Producing and Marketing the Only Such Vaccine Licensed as Safe and Effective for Use

In 1934 there were 265,000 reported cases of pertussis in the United States and 7,500 related deaths.[17] By the early 1940's, pertussis caused two and one-half times the number of deaths attributed to measles, mumps, rubella, diphtheria, polio, meningitis, chicken pox, and scarlet fever, *combined*.[18] In 1944 the federal government began to license and regulate the manufacture of a newly developed whole-cell pertussis vaccine. Widespread immunization was so successful that, in 1985, the CDC reported that "during the last ten years, . . . annual averages of 1,835 cases and ten fatalities have occurred."[19] In contrast, the CDC estimates that 353,000 cases of pertussis and 450 related deaths would occur every year in the United States if it were not for the administration of this effective vaccine.[20]

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[17] See HHS *Amicus* Brief, Appendix H at 42a (citing Hinman & Koplan, *Pertussis and Pertussis Vaccine: Reanalysis of Benefits, Risks and Costs*, Journal of the American Medical Association (June 15, 1984) (hereinafter "Hinman & Koplan")).

[18] *Id.*

[19] *See* Centers for Disease Control—Immunization Practices Advisory Committee, *Diphtheria, Tetanus, and Pertussis: Guidelines for Vaccine Prophylaxis and Other Preventive Measures*, Morbidity and Mortality Weekly Report (July 12, 1985) at 406, *cited in* HHS *Amicus* Brief, Appendix H at 42a.

[20] *See* HHS *Amicus* Brief, Appendix H at 45a (citing Hinman & Koplan, at 3112).

Since at least 1962 and the passage of the Vaccination Assistance Act,[21] the federal government has taken the lead in promoting nationwide immunization. The 1962 Act, proposed and passed in light of what were considered "excellent vaccines," [22] reflected a federal initiative "to stamp out four serious diseases—poliomyelitis, diphtheria, whooping cough [pertussis], and tetanus." [23] Congress went beyond merely authorizing the marketing of these vaccines; it launched an aggressive program actively to encourage their use. Both the House Report and the Senate Report expressed concerns about incomplete immunization and embraced the objective of maximizing nationwide coverage.[24]

Subsequent congressional enactments reflect a continuing promotional attitude toward immunization. The Senate Committee Report on the Communicable Disease Control Amendments Act of 1972 [25] noted Congress' "unmistakable affirmation . . . that the Federal Government has a continuing responsibility" and a "leadership role"

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[21] Pub. L. No. 87-868, 76 Stat. 1155 (1962).

[22] *See, e.g., Preliminary Report of Progress in the Review of the Vaccination Picture in the Nation, reprinted in* 108 Cong. Rec. 11,745, 11,745 (1962).

[23] *Intensive Immunization Programs: Hearings on H.R. 10541 Before the House Comm. on Interstate and Foreign Commerce,* 87th Cong., 2d Sess. 44 (1962) (statement of Abraham Ribicoff, Secretary of Health, Education and Welfare).

[24] The Senate Report described the need for a "two-stage national effort," including "intensive" vaccination compaigns aimed at all unvaccinated, susceptible persons, followed up with a strengthening of ongoing vaccination programs. S. Rep. No. 1907, 87th Cong., 2d Sess. *reprinted in* 1962 U.S. Code Cong. & Admin. News 3970, 3978. The House Report echoed the desire to "administer the vaccine to substantially all of the population in the United States," in order to avoid the "totally unnecessary risk" of epidemics. H.R. Rep. No. 1835, 87th Cong., 2d Sess. 3 (1962).

[25] Pub. L. No. 92-449, 86 Stat. 748 (1972).

in the prevention of contagious diseases.[26] In 1978, a Senate Committee Report, noting the disparity between the 60 percent national immunization rate and the federal goal of 90 percent immunization, approved new funding levels that "should allow HEW to make certain that 90 percent of American children are immunized against polio, rubella, measles, pertussis, diphtheria, typhoid, and mumps."[27] In 1982, a House Committee Report, approving further funding, noted with pride the success of Congress' "Childhood Immunization Initiative," the purpose of which was "to raise immunization levels against polio, measles, rubella, diphtheria, tetanus, mumps, and pertussis and to establish a permanent system to provide comprehensive immunization services to the more than 3 million children born in the United States each year."[28]

The whole-cell pertussis vaccine has been indispensable in achieving federal goals; indeed, it is the only type of pertussis vaccine currently licensed by the FDA[29] for use in this country.[30] The FDA, the CDC, and the National Institutes of Health ("NIH") have, for almost 40 years, "promoted vaccination of the populace with diph-

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[26] S. Rep. No. 825, 92d Cong., 2d Sess., *reprinted in* 1972 U.S. Code Cong. & Admin. News 3430, 3433, 3434, 3436.

[27] S. Rep. No. 1196, 95th Cong., 2d Sess. 6, 37 (1978).

[28] H.R. Rep. No. 1063, 98th Cong., 2d Sess. 2 (1984).

[29] In 1962, the FDA granted to Eli Lilly and Company a license to produce a non-whole-cell pertussis vaccine. Lilly stopped marketing its "fractionated-cell" vaccine in 1977 and later requested revocation of its license to produce that vaccine. The FDA did revoke that license and has subsequently indicated its disinclination, based on current scientific evidence, to license any non-whole-cell pertussis vaccine. *See infra*, notes 35-36 and accompanying text; *see also* HHS *Amicus* Brief, Appendix H at 46a-47a.

[30] Federal law makes it a crime to produce and distribute in the United States any vaccine that is not licensed by the FDA. *See* 21 U.S.C. §§ 331(d), 333(a), 355(a) (1982); 42 U.S.C. § 262(f) (1982).

theria-tetanus-pertussis (DTP) vaccines containing as one of their components the so-called 'whole-cell' pertussis vaccine." [31] These HHS agencies, while aware that the whole-cell vaccine "may have serious adverse side effects for a small number," have promoted use of the whole-cell vaccine "because of its proven value for millions of children." [32]

The federal government not only *promotes* use of the whole-cell vaccine, it actually *purchases*, through the CDC, large quantities of whole-cell vaccine, which it then distributes for use in state health clinics or which it stockpiles for emergencies.[33] The funds for these purchases have been provided by Congress, notwithstanding extensive public debate about the safety of the whole-cell vaccine. Indeed, in arriving at recent funding levels, one Senate Report explained that "the Committee intends to assure high levels of immunization, . . . and to provide support for D.P.T. vaccination programs," even though the Committee "is also aware that there is growing concern about the safety of vaccine products . . . ." [34]

This same concern for safety underlies the federal involvement, through HHS, in alternative pertussis vaccine research throughout the world. The HHS *Amicus* Brief describes HHS's funding of, participation in, and monitoring of that research and, in no fewer than five separate passages, recites HHS's explicit rejection of the proposition that there exists a non-whole-cell vaccine that is

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[31] HHS *Amicus* Brief, Appendix H at 39a.

[32] *Id.*

[33] In one recent twelve-month period, the federal government purchased for distribution nine million doses of the whole-cell vaccine, *see* HHS *Amicus* Brief, Appendix H at 53a, n.12, or nearly 50% of all of the DTP vaccine required to meet the country's need. *See id.* at 54a. The government purchases additional quantities for an emergency stockpile. *See id.* at 53a.

[34] S. Rep. No. 393, 98th Cong., 2d Sess., *reprinted in* 1984 U.S. Code Cong. & Admin. News 4804, 4817.

known to be safe and effective.[35] HHS categorically states that

> based on their evaluation of the available scientific and medical evidence, HHS's public health experts have concluded that alternative pertussis vaccines have not yet been adequately shown to be safe and effective for licensure in the United States.[36]

Invoking Virginia common law and federal diversity jurisdiction, respondent seeks to persuade a sympathetic jury to reject HHS's conclusion and award ten million dollars in damages against petitioner for producing, in compliance with federal standards, the only pertussis vaccine licensed and promoted for use by the federal government.[37] Large verdicts are not uncommon in this field,[38]

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[35] *See* HHS *Amicus* Brief, Appendix H at 39a, 41a, 45a, 51a, 54a-55a.

[36] *See* HHS *Amicus* Brief, Appendix H at 51a. In extended passages, HHS describes its specific reservations about both the fractionated-cell vaccine and the acellular vaccine. *See id.* at 45a-51a.

[37] The difficulty that jurors have in resolving the technical issues involved, and, more significantly perhaps, jurors' understandable sympathy for the few unfortunate victims of a beneficial public health program, is illustrated by the incongruous special verdicts rendered by an Idaho jury in a recent DTP design defect case. That jury specifically found that the whole-cell vaccine was not "in a defective condition unreasonably dangerous to persons," but also found that the manufacturer was negligent in using the whole-cell design rather than developing a different design. That jury awarded the plaintiff $1.1 million. *See Toner v. Lederle Laboratories*, 779 F.2d 1429 (9th Cir. 1986), *certified questions addressed*, 112 Idaho 328, 732 P.2d 297, *disposition completed*, 828 F.2d 510 (9th Cir.), *original opinion amended*, 831 F.2d 180 (9th Cir. 1987), *cert. denied*, 108 S. Ct. 1122 (1988).

[38] In addition to the $1.1 million damage award in *Toner*, *id.*, a Kansas jury recently awarded a plaintiff $15 million in compensatory damages on a whole-cell design defect claim. *See Graham v. Wyeth Laboratories, Inc.*, No. 85-1481-K (D. Kan. Oct. 15, 1987). *See also Johnson v. American Cyanamid Co.*, 239 Kan. 279, 718 P.2d 1318 (1986) ($10 million verdict on polio vaccine design defect claim).

and Congress has recognized that continuation of this trend could lead manufacturers to withdraw from the vaccine business.[39] This Court itself has recently recognized that such damage claims inevitably lead manufacturers to raise prices substantially or to discontinue production altogether. *See Boyle v. United Technologies Corp.*, 108 S. Ct. 2510, 2515, 2518 (1988).[40] Indeed, whole-cell DTP vaccine prices have increased 2,300% over the past six years.[41] This case thus offers the Court an opportunity to determine whether the Supremacy Clause preempts an application of state law that would jeopardize a crucial federal public health program.

Petitioner has not contended, and, if certiorari were granted, would not argue to this Court, that federal law broadly preempts all state law damage claims for vaccine-related injuries.[42] The imposition of damages for

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[39] *See* H.R. Rep. No. 908, 99th Cong., 2d Sess. (1986), Part 1, at 6-7.

[40] As Judge Wilkins noted in his concurring opinion below, vaccine litigation has already increased the price of vaccines and

> particularly regarding the DTP vaccine, manufacturers are reconsidering their future role in the vaccine market. . . . [Petitioner] is one of the only two [companies] which manufactures the DTP vaccine. The withdrawal of any manufacturer from the market poses a serious threat to public health, in the form of vaccine shortages with resulting decreased immunization and a possible resurgence of these diseases.

844 F.2d at 1116, Appendix A at 14a.

[41] Because of uncertainties over the degree to which the 1986 Act will reduce liability exposure and the imposition of a large federal excise tax to finance the no-fault compensation program, the after-tax price for the vaccine, including the excise tax, has increased even since the enactment of the new law.

[42] Petitioner's argument is thus significantly narrower than the argument rejected in *Hurley v. Lederle Laboratories*, No. 87-2578 (5th Cir. Aug. 17, 1988), another case involving a whole-cell DTP design defect claim. *See infra* Section II.

the defective manufacture or the negligent administration of a vaccine does not stand as an obstacle to federal immunization objectives, since defective manufacture and negligent administration are correctible without removing a critical vaccine from the market. In this case, however, respondent seeks to impose state tort liability for producing, in compliance with federal government standards, the only type of pertussis vaccine that the federal government considers safe and effective enough for licensing. Petitioner would argue to this Court that the imposition of state tort liability under these circumstances, with its attendant impact on vaccine prices and availability, stands as an unconstitutional obstacle to federal objectives and that respondent's design defect claim is therefore preempted.[43]

B. The 1986 Act Does Not Alter the Preemptive Effect of Prior Federal Legislation on Design Defect Claims Arising from Pre-October 1988 Vaccinations

Respondent's principal argument has focused on the 1986 Act's provision that "State law shall apply" to damage claims for vaccine-related injuries.[44] The 1986 Act, however, applies only to vaccinations occurring on or after October 1, 1988.[45] Therefore, any change the 1986 Act might be thought to make as to the preemptive effect

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[43] To a large extent, respondent's warning claims, which the district court also held to be preempted, are merely variants of her design defect claim. For example, respondent claims that petitioner should have included in its warning a statement that "there were different formulations for a less-than-whole-cell vaccine described in the literature for many years, which formulations made the pertussis vaccine less reactogenic." Response to Defendant's Supplemental Memorandum in Support of Summary Judgment, Appendix J at 57a. To the extent respondent's warning claims mirror her design claims, the Court should also consider whether the warning claims are preempted.

[44] 42 U.S.C.A. § 300aa-22(a) (West Supp. 1988).

[45] *See* 42 U.S.C.A. § 300aa-1 note.

of pre-existing federal law would not rescue respondent's design defect claim for a 1983 vaccination from preemption under earlier federal law.[46] Moreover, to whatever extent the 1986 Act is informative as to the existence of a preemption under earlier federal laws, it can hardly be read to mean that earlier federal laws in effect at the time of the 1983 vaccination implicitly denied petitioner even the limited preemptive effect that the federal defense in the 1986 Act extends to claims based on vaccinations occurring after its effective date.

The majority below recognized that the pertinent provisions of the 1986 Act were not in effect at the time of respondent's alleged injury or at the time respondent filed this suit.[47] Nonetheless, the majority reasoned that the legislative history of the 1986 Act indicated that Congress "acted with the understanding" that state tort actions for vaccinations occurring before October 1, 1988, "are available without preemption by earlier federal legislation." [48] The majority therefore concluded that pre-

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[46] Even if pre-existing federal law is held to preempt respondent's state law design defect claim, respondent may still pursue federal no-fault compensation under the 1986 Act. Even though she alleges an injury arising from a vaccination before the 1986 Act, that Act permits her, before judgment, to withdraw her action without prejudice and file a petition for compensation. *See* 42 U.S.C.A. §§ 300aa-11(a)(5), 300aa-15(a), (b) (West Supp. 1988). Congress has authorized appropriations of $80 million for each of the fiscal years 1989-1992, inclusive, for compensation for such pre-Act injuries. *See* 42 U.S.C.A. § 300aa-15(j) (West Supp. 1988).

[47] 844 F.2d at 1111, Appendix A at 38a.

[48] 844 F.2d at 1113, Appendix A at 8a. The lower court's use of subsequent legislative history in divining the intent of earlier legislation is not only "anachronistic," as the lower court itself put it, *id.* at 1111, it is also very dubious. This Court has reasoned that "subsequent legislation usually is not entitled to much weight in construing earlier statutes," *Mattz v. Arnett*, 412 U.S. 481, 505 n.25 (1973), *citing United States v. Southwestern Cable Co.*, 392 U.S. 157, 170 (1968), and that "[t]he views of a subsequent Congress form a hazardous basis for inferring the intent of an earlier

existing federal law did not preempt vaccine-related injury claims based on vaccinations occurring before October 1, 1988, even to the limited extent of the federal defense provided by the 1986 Act.

Petitioner does not dispute the *general* availability of state tort actions for vaccine-related injuries occurring before or after October 1, 1988. Petitioner contends only that there is a narrow class of tort claims—including those at the core of this case—that was preempted by earlier federal legislation as to pre-October 1988 vaccinations and that remains preempted even under the 1986 Act as to vaccinations on and after October 1, 1988. The 1986 Act, by establishing a specific federal defense for properly prepared vaccines that are unavoidably unsafe, expressly precludes the application of state law in one class of cases that might well include future attempts to litigate design defect issues of the type raised here:

> [N]o vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death . . . if the injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared . . . .[49]

The precise scope and application of this specific federal "comment k" defense has, of course, not yet been determined.[50] But it makes no sense to read the 1986 Act,

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one." *Russello v. United States*, 464 U.S. 16, 26 (1983), *quoting United States v. Price*, 361 U.S. 304, 313 (1960). *See also, United States v. Clark*, 445 U.S. 23, 33 n.9 (1980); *United States v. Philadelphia Nat'l Bank*, 374 U.S. 321, 349 (1963); *Rainwater v. United States*, 356 U.S. 590, 593 (1958); *United States v. United Mine Workers*, 330 U.S. 258, 281-82 (1947).

[49] 42 U.S.C.A. § 300aa-22(b)(1) (West Supp. 1988).

[50] As previously noted, *supra* note 13, the new federal defense is modeled on comment k to the Restatement (Second) of Torts, § 402A, which precludes strict liability in tort for highly beneficial products that are unavoidably unsafe even when properly manufactured. The precise scope and manner of comment k's application vary widely among the states that adhere to its principle. In Idaho,

as the majority below seems to have done, to mean that pre-existing federal law did not preempt state law design defect claims at least to the same extent as the 1986 Act, when the 1986 Act itself contains a provision that appears to afford a similar preemption for vaccinations occurring after its effective date.

Whatever its ultimate construction, this unambiguous federal displacement of state law in the 1986 Act belies the notion, apparently adopted by the court below, that Congress was content to leave entirely to state courts where to strike the balance between the federal public interest in vaccine availability and an injured claimant's right to sue for an alleged design defect of the type involved here. Rather, Congress clearly decided that certain "unavoidably unsafe" vaccines should not be driven from the market by the threat of state tort liability based on such claims. The limited preemption argument that petitioner seeks to present to this Court is a necessary corollary to that congressional determination: where only one vaccine design is approved, licensed, purchased, and promoted for use by the federal government, and the responsible federal agencies are unwilling—based on scientific evidence—to license the alternatives respondent claims to be superior, federal policy requires preemption of state design defect claims and supports the district court's summary judgment for petitioner on the record of this case.

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for example, under comment k, even a jury finding that a vaccine or drug is unavoidably unsafe apparently does not preclude the imposition of liability for negligently failing to design a safer product. *See Toner, supra* note 37. In contrast, California applies comment k to render all properly prepared prescription drugs unavoidably unsafe as a matter of law and thus to preclude design defect claims as to those drugs. *See Brown v. Superior Court*, 44 Cal. 3d 1049, 751 P.2d 470, 245 Cal. Rptr. 412 (1988). The role of comment k in Virginia law has yet to be fully developed or explored by Virginia courts, *cf. Lust v. Clark Equipment Co.*, 792 F.2d 436 (4th Cir. 1986); *Bly v. Otis Elevator Co.*, 713 F.2d 1040, 1045 n.6 (4th Cir. 1983), and was not raised in or discussed by the district court below.

C. The 1986 Act Does Not Diminish the Importance of This Case

Hundreds of vaccine damage suits are currently pending—most of which involve the DTP vaccine—with damage claims totaling several billion dollars.[51] Most of these cases include design defect claims similar to the one made here. All of them involve vaccinations occurring before October 1, 1988, the effective date of the 1986 Act. The outcome of these cases is of crucial importance to the financial stability of the vaccine manufacturing industry and stands as a major barrier not only to the ability of existing firms to remain in business, but also to the entry of additional firms.[52]

This case also has federal public health policy ramifications that go beyond the lawsuits arising out of vaccinations occurring before the effective date of the 1986 Act. If this Court upholds the district court's summary judgment on the ground that federal legislation preceding the 1986 Act implicitly preempts state law design defect claims that are expressly preempted by the 1986 Act, the decision will also have a major impact on the state law design defect cases arising out of future vaccinations covered by the 1986 Act.

Moreover, the 1986 Act applies only to seven named childhood vaccines—tetanus, diphtheria, pertussis, measles, rubella, polio and mumps. Other licensed childhood vaccines and adult vaccines,[53] and other vaccines that may be licensed in the future (such as for AIDS), are not subject to the 1986 Act, but only to preexisting vac-

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[51] *See* House Subcomm. on Health and the Environment, 99th Cong. 2d Sess., *Childhood Immunizations*, 85-86 (Comm. Print 1986).

[52] As previously noted, even the existence of the 1986 Act has not kept the price of the whole-cell vaccine from continuing to climb. *See supra* note 41 and accompanying text.

[53] Among the other vaccines currently licensed by the FDA are anthrax, cholera, BCG (tuberculosis), and typhoid vaccines.

cine legislation. All manufacturers of such vaccines, no matter how strongly the federal government regulates, promotes and finances their use, are and will continue to be subject to the same type of state law design defect claim as the claim presented in the instant case, even when the federal government has not yet licensed any of the allegedly superior alternative designs. The question of whether such claims are preempted by federal legislation will continue to be of critical importance to federal public health policy and to the willingness of manufacturers to continue making currently licensed vaccines or to embark on making those newly licensed hereafter. That question should therefore be considered and resolved by this Court.

II. THE COURT SHOULD GRANT CERTIORARI BECAUSE THE LOWER COURT'S REASONING CONFLICTS IN A CRITICAL RESPECT WITH THE REASONING OF A RECENT FIFTH CIRCUIT DECISION

The decision of the Fourth Circuit below establishes as the law of the case that federal vaccine legislation in effect at the time of respondent's vaccination has no preemptive effect whatsoever on state tort law. In a case just decided on August 17, 1988, the Fifth Circuit reached a different conclusion. *Hurley v. Lederle Laboratories*, No. 87-2578 (5th Cir. Aug. 17, 1988).[54] While the *Hurley* court agreed with the Fourth Circuit that federal vaccine legislation in effect at that time did not totally preempt state tort law (as the district court in *Hurley* had decided), it remanded to the district court the question of whether such legislation preempted state tort law at least as to the same whole-cell pertussis design defect claim made by respondent in this case.[55]

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[54] The *Hurley* decision is attached as Appendix K to this petition.

[55] *See* Appendix K at 70a n.4. The *Hurley* court also ruled that federal vaccine legislation impliedly preempted an inadequate warn-

The Fifth Circuit stated that "our holding against general preemption does not necessarily exclude the possibility of such a specific preemption." [56] Because of the "federal interest in encouraging manufacturers to produce vaccines" and the need to provide those manufacturers with "some assurance that if they follow certain prescribed procedures, . . . they are complying with the law," [57] the *Hurley* court concluded that it "would seem likely" that FDA approval of the existing whole-cell vaccine would impliedly preempt design defect claims, just as it impliedly preempted inadequate warning claims,[58] "assuming that the FDA processed all necessary and available data . . . ." [59] The *Hurley* court remanded this issue to the district court in the absence of a record addressed to that point.

The record in this case, however, is complete enough to support just such a narrow preemption ruling. The HHS *Amicus* brief shows that the FDA is intimately involved in alternative pertussis vaccine research throughout the world and is cognizant of all the "necessary and available data" relevant to its vaccine licensing decisions. Based on that data, the FDA not only has approved the continued marketing of petitioner's whole-cell vaccine as safe and effective, it also has affirmatively rejected the proposition that the alternatives to the whole-cell vaccine now under study have been shown to be safe and effective for licensure in the United States.

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ing claim when the actual warning contained the precise language approved by the FDA and no more, as the applicable federal legislation requires, absent evidence that the manufacturer withheld relevant information from the FDA. *See* Appendix K at 68a-70a.

[56] Appendix K at 70a n.4.

[57] Appendix K at 70a.

[58] *See supra* note 55.

[59] Appendix K at 70a n.4.

The court below completely rejected the possibility of preemption even in these narrow circumstances. The lower court's reasoning thus conflicts with the *Hurley* court's reasoning and the two circuits have sent fundamentally conflicting messages to the district courts to which the cases have been remanded. The conflict is palpable and appropriate for resolution in this case, since this case presents precisely the type of record that the *Hurley* court said "would seem likely" to require a finding of limited implied preemption. Accordingly, this Court should reverse the decision of the Fourth Circuit below and either find such a limited preemption on the present record or direct a remand of that issue to the district court.

III. THE COURT SHOULD GRANT CERTIORARI TO REMEDY THE CONFLICT BETWEEN THE LOWER COURT'S DECISION AND THIS COURT'S RECENT HOLDING IN *BOYLE V. UNITED TECHNOLOGIES CORP.* THAT FEDERAL APPROVAL OF SPECIFICATIONS FOR PRODUCTS PURCHASED BY THE FEDERAL GOVERNMENT AND ESSENTIAL TO CARRYING OUT GOVERNMENT POLICY PREEMPTS DESIGN DEFECT CLAIMS

This Court has long held that federal law preempts any application of state law that would frustrate federal objectives. *See Hines v. Davidowitz*, 312 U.S. 52, 67 (1941); *San Diego Bldg. Trades Council v. Garmon*, 359 U.S. 236, 246-47 (1959). Recently, in *Boyle v. United Technologies Corporation*, 108 S. Ct. 2510 (1988), this Court made plain that where the federal government, in furtherance of federal objectives, procures products designed to federally mandated or federally approved specifications, and such procurement is threatened by state law design defect claims, federal law displaces state law even in disputes to which the government is not a party. While *Boyle* involved a claimed design defect in a helicopter procured for the military, the essence of the *Boyle*

rationale applies to DTP design defect claims with equal force, whether or not the particular dose of vaccine was purchased under a government contract.

In *Boyle*, this Court discerned that the federal government had a concrete interest in design defect litigation where the imposition of liability on the government's suppliers would "directly affect" government contracts, either by causing the supplier to "decline to manufacture the design specified by the government," or to raise its price.[60] The Court recognized that the government's interest may be just as concrete even where the supplier itself develops the design in question, since the design "may well reflect a significant policy judgment by Government officials whether or not the contractor rather than those officials developed the design." [61]

And just as "the selection of the appropriate design for military equipment to be used by our Armed Forces is assuredly a discretionary function within the meaning of [the Federal Tort Claims Act]," so, too, the approval and licensing of the appropriate design for the pertussis vaccine is a discretionary function.[62] As with helicopter designs, approval of a vaccine design involves balancing many technical, scientific and even social details, including a determination of the optimum balance of safety and effectiveness. The federal government approves the whole-cell design and purchases it in furtherance of fed-

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[60] 108 S. Ct. at 2515.

[61] 108 S. Ct. at 2518.

[62] FDA regulations provide that a product license shall be issued only upon examination of the product and "upon a determination, by the Director, Office of Biologics Research and Review" that the product meets applicable standards. 21 C.F.R. §§ 601.4, 601.20. Petitioner stands ready to demonstrate to this Court that the manner and method of determining compliance with the applicable standards involves agency judgment of the kind protected by the discretionary function exception. *Cf. Berkovitz v. United States*, 108 S. Ct. 1954, 1963 & n.11 (1988).

eral immunization objectives, just as surely as the government approves helicopter designs and purchases them in furtherance of federal defense objectives.

This Court reasoned in *Boyle* that such design judgments, whether made by the government or made by suppliers and approved by the government, effectively become the government's to the extent that the government willfully uses or facilitates the use of the resulting design in pursuit of its policy objectives. The Court concluded that "second-guessing" such judgments "through state tort suits against contractors would produce the same effect sought to be avoided by the FTCA exemption [for discretionary functions]," either by causing the costs of such suits to be passed on to the government or by causing suppliers to stop producing the product.[63]

DTP design defect claims involve just such "second-guessing" of essentially federal judgments. Even though the dose of vaccine administered to respondent was not sold under a government contract, petitioner sells large quantities of DTP vaccine under government contracts, and its ability to continue to do so would be directly imperiled by adverse judgments in cases like this one. The court of appeals disregarded this point and reached a conclusion directly contrary to that mandated by the *Boyle* rationale. This Court should, with the benefit of briefing and argument, fully consider the nature of the conflict between the *Boyle* decision and the decision below.

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[63] 108 S. Ct. at 2517-18.

CONCLUSION

For the foregoing reasons, the petition for a writ of certiorari should be granted.

Respectfully submitted,

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August 23, 1988

APPENDICES

APPENDIX A

UNITED STATES COURT OF APPEALS
FOURTH CIRCUIT

No. 87-1578

TRACY ISABEL ABBOT, a minor who sues by her mother and next friend DEBORAH ABBOT,
Plaintiff-Appellant,

v.

AMERICAN CYANAMID CO., a Maine Corp.,
Defendant-Appellee,

PHARMACEUTICAL MANUFACTURERS ASSOCIATION;
AMERICAN ACADEMY OF FAMILY PHYSICIANS;
UNITED STATES OF AMERICA,
Amici Curiae.

Argued Jan. 4, 1988

Decided April 20, 1988

Before MURNAGHAN, SPROUSE, and WILKINS, Circuit Judges.

MURNAGHAN, Circuit Judge:

Plaintiff, Tracy Abbot, whose name throughout is sometimes inconsistently spelled as "Abbott", is a four year old child suffering neurologic injuries. She alleges that they result from inoculation in August 1983 of Tri-Immunol, diptheria-tetanus-pertussis (DTP) vaccine manufactured by Lederle Laboratories, a division of defendant American Cyanamid Co. Plaintiff brought suit under three counts: (1) strict liability, (2) breach of implied warranty of merchantability and (3) negligence. In the

course of the summary judgment proceedings, plaintiff limited her claims to: (1) breach of warranty in two manners (a) failure to warn and (b) defective design, and (2) the tort of negligent design.

The district court granted summary judgment on all claims to defendant. First, it held that plaintiff's rights under state law were preempted by federal law. Second, the court granted judgment, on an alternate basis, to defendant on plaintiff's failure to warn claim because plaintiff's administering physician, who was a "learned intermediary," testified on deposition that the warnings were adequate.

1. *Whether federal law preempts imposition of state common law liability for defective design or failure to warn upon a manufacturer of a vaccine.*

The doctrine of federal preemption of state law arises under the supremacy clause of the United States Constitution, art. VI, cl. 2. Preemption occurs in any of three manners: (1) Congress may pass a statute that by its express terms preempts state law, (2) Congress, though not expressly so stating, may imply that it is preempting state law by occupation of an entire field of regulation, so that no room is left for supplementary state regulation, (3) Congress may speak neither expressly nor impliedly of preemption, nonetheless state law is preempted to the extent it actually conflicts with federal law; such a conflict occurs when (a) compliance with both state and federal law is impossible or (b) when state law stands as an impediment to a federal purpose. *Michigan Canners and Freezers Assoc. v. Agricultural Mktg. and Bargaining Bd.*, 467 U.S. 461, 469, 104 S.Ct. 2518, 2522-23, 81 L.Ed.2d 399 (1984).

Defendant discerns preemption of plaintiff's claims from the Public Health Service Act, 42 U.S.C. §§ 201-300 (PHSA) and the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-392 (FDCA) of which the enactments both predate the regrettable 1983 incident. Defendant

argues for preemption most strongly under manner 3(b), frustration of a federal purpose, its so-called narrow preemption argument, though it alternatively argues that manner 2 is satisfied also, its broad preemption argument. Defendant makes no argument that Congress, in the period relevant to the present case, has expressly displaced state law regarding vaccines. Plaintiff argues the contrary, that Congress has expressly provided the opposite, *i.e.*, that state remedies apply. Plaintiff discerns the argument from the National Childhood Vaccine Injury Act of 1986, Pub. L. 99-660, 100 Stat. 3755 (1986), (1986 Act) and its legislative history.

In the 1986 Act, Congress created an administrative "no-fault" program to compensate children injured by vaccines. The 1986 Act directed that children would have access to state remedies but with certain restrictions for injuries resultant from vaccinations administered after the 1986 Act's effective date. The effective date of the pertinent provisions of the 1986 Act is the date of enactment of a special tax to finance the compensation program. The 1986 Act did not provide a funding tax, but part of the Omnibus Budget Reconciliation Act of 1987 (Budget Act) did. A manufacturers' excise tax was placed on certain vaccines to fund the Vaccine Injury Compensation Trust Fund. The Budget Act also contains the Vaccine Compensation Amendments of 1987 (1987 Act) that establish October 1, 1988 as the effective date for the compensation system and limitation upon state law for vaccinations occurring after that date.

Plaintiff's argument is anachronistic, for it uses subsequent legislation in construing the preemptive effect of the earlier, PHSA and FDCA, statutes. While anachronistic, the approach is not without support; the Supreme Court has on occasion found evidence of Congress' intent concerning a statute at the time of its enactment embodied in subsequent actions regarding the statute. *Grove City College v. Bell*, 465 U.S. 555, 567, 104 S.Ct. 1211,

1218, 79 L.Ed.2d 516 (1984). Since the 1986 Act is an amendment to the PHSA the exception might apply. We need not decide what effect the 1986 Act has, as plaintiff claims, for determining the preemptive intent of the PHSA and FDCA, for even without consideration of what we should draw from the allowance of state based actions in the 1986 Act, we conclude that, considering the PHSA and FDCA alone, Congress did not intend, either expressly or impliedly, to preempt state law.

Defendant's broad preemption theory is that pervasive federal regulation of vaccines reflects a federal purpose to occupy the field of vaccine design and labeling. Defendant's narrow theory is that the national public health purposes and objectives underlying the PHSA would be frustrated if potentially ruinous liability could be imposed under state law for manufacturing the only type of pertussis (whooping cough) vaccine approved by the federal government rather than a different type of vaccine that is not now and might never be federally approved. Defendant argues that preemption under its narrow theory is most clear as against design defect and failure to warn claims, as plaintiff alleges in the present case, in contrast to claims of improper manufacture, distribution or testing. We first consider the broad theory, then the narrow.

The FDA's regulation of prescription drugs and biological products is comprehensive. The DPT vaccine is a prescription biological product subject to the provisions of the FDCA, the PHSA, and regulations promulgated thereunder. The FDA regulations encompass the licensing, production, testing, distribution, labeling, review and approval of all drugs and biologicals. Each DPT manufacturer must be licensed, must submit detailed description of and receive FDA approval of its manufacturing process, must permit FDA inspection of its manufacturing facilities, meet personnel qualifications, and conduct and submit results of quality assurance tests to the FDA

for each batch of vaccine. 21 C.F.R. §§ 600.20, 601.1, 601.2, 601.25, 610.1, 620.1-620.7.

The FDA requires that the label or package insert for a biological product contain among others: (1) the composition of the product; (2) the product's administration schedule; (3) indication and contraindication of product usage; and (4) potential adverse reactions associated with the product's use. 21 C.F.R. §§ 201.50-.57, 610.60-.65. The language of the label is subject to FDA approval, and once approved, cannot be changed without FDA approval. 21 C.F.R. § 601.12.

Preemption does not follow immediately from the comprehensive federal regulation of prescription biological products. Every subject that merits congressional legislation is, by definition, a subject of national concern. That cannot mean, however, that every federal statute ousts all related state law. *Hillsborough County v. Automated Med. Labs*, 471 U.S. 707, 719, 105 S.Ct. 2371, 2378, 85 L.Ed.2d 714 (1985). Defendant has several canons of interpretation and presumptions set against it. When Congress does not expressly state its intent, there is a presumption against preemption. *Maryland v. Louisiana*, 451 U.S. 725, 726, 101 S.Ct. 2114, 2118-19, 68 L.Ed.2d 576 (1981). The presumption is even stronger with state or local regulation of matters related to health and safety. *Hillsborough*, 473 U.S. at 715, 105 S.Ct. at 2376. Courts are more reluctant to infer preemption from the comprehensiveness of regulations than from the comprehensiveness of statutes. *Id.* at 717, 105 S.Ct. at 2377. When preemption by regulation is considered, courts are reluctant to find preemption by federal regulations when the agency does not make very clear an intent of preemption since agencies normally address problems in a detailed manner. *Id.* at 718, 105 S.Ct. at 2377-78. The presumption against preemption is even stronger against preemption of state remedies, like tort recoveries, when no federal remedy exists. *Silkwood v. Kerr-McGee Corp.*,

464 U.S. 238, 251, 104 S.Ct. 615, 622-23, 78 L.Ed.2d 443 (1984). All of those work against preemption in the present case. We agree with the majority of courts addressing the issue that Congress has not impliedly preempted state regulation of vaccine manufacture.[1]

Defendant's narrow preemption argument, that the national public health purposes would be frustrated by potentially ruinous state law tort liability, is also incorrect. A decision about preemption on that ground requires the court independently to consider national interests and their putative conflict with state interests. While preemption under a theory of express or implied preemption is essentially a matter of statutory construction, preemption under a frustration of federal purpose theory is more an exercise of policy choices by a court than strict statutory construction. An independent judgment that federal purposes require preemption comes in the face of congressional silence, both express and implied, on the subject.

The overall goal of the PHSA and FDCA is the safety of drugs and biologic products. That goal is more enhanced than frustrated by state law. However, the federal government has favored not only vaccine safety but also availability and use. Availability and use of vac-

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[1] The overwhelming majority of courts considering federal preemption of state law as regards vaccines have found no preemption. *Foyle v. Lederle Laboratories*, 674 F.Supp. 530 (E.D.N.C. 1987), *petition for permission to pursue interlocutory appeal filed in this Court* Dec. 3, 1987 (No. 87-8119); *Percival v. American Cyanamid Co.*, —— F.Supp. ——, No. CIV-85-2671-P (W.D.Ok. Nov. 25, 1987); *Scholl v. Lederle Laboratories*, —— F.Supp. ——, No. CIV 85-409 TNC-RMB (D.Ariz. Nov. 10, 1987); *Morris v. Parke, Davis & Co.*, 667 F.Supp. 1332 (C.D.Cal. 1987); *MacGillivray v. Lederle Laboratories*, 667 F.Supp. 743 (D.N.M. 1987); *Graham v. Wyeth Laboratories*, 666 F.Supp. 1483 (D.Kan. 1987); *Wack v. Lederle Laboratories*, 666 F.Supp. 123 (N.D. Ohio 1987); *Patten v. Lederle Laboratories*, 655 F.Supp. 745 (D. Utah 1987). Only the court in *Hurley v. Lederle Laboratories*, 651 F. Supp. 993 (E.D. Tex. 1986) and the district court in the present case have found federal preemption.

cines can be frustrated by state tort law. The issue then is whether the federal interest requires that federal regulation be viewed as having struck the balance between safety and quantity or whether the regulations merely establish minimum safety standards and allow state regulation to establish the balance. *See Hillsborough*, 471 U.S. at 721, 105 S.Ct. at 2379 (The Court responded to a similar preemption argument and decided that federal regulation of blood plasma collection did not strike the balance of safety and quantity, but only provided minimum standards).

In deciding the issue of whether federal law should strike the balance or allow states to, it is appropriate to consider the National Childhood Vaccine Injury Act of 1986. As indicated earlier, we assume the 1986 Act is of no relevance in construing the preemptive intent of earlier federal legislation like the PHSA and FDCA. That conclusion is important when considering whether Congress expressly or impliedly preempted state law in those statutes.

We must decide whether the federal interest in vaccine safety and quantity is frustrated by coexisting state regulation. Thus, it is appropriate to look at recent views on federal policies regarding the balance of vaccine availability and safety especially those enunciated by the Congress. The Childhood Vaccine Injury Act of 1986 speaks to this balance with clarity. Congress created a "no-fault" compensation program as an alternate to state tort and contract recoveries. The legislative history of the Vaccine Compensation Amendments of 1987 make even more clear that at the time of passage of the 1986 and 1987 Acts Congress acted with the understanding that state tort and contract remedies were available and that they continue to be available as modified by the Acts.

Congress, when it addressed vaccines in 1986 and 1987, did not preempt state law. Further, to the extent

that the Acts state congressional views about the preemptive effect of earlier legislation, the Acts and their legislative history assume that earlier legislation was of no preemptive effect. Defendant argues that the 1986 Act did not reject preemption, rather it is neutral on the issue leaving the preemption issue exactly as it stood before the 1986 Act. Defendant supports the argument in the only way it can, by noting that the word "preemption" cannot be found in any of the 1986 Act legislative materials, therefore, it was not addressed. While the premise is true, the conclusion is not. The 1986 Act is replete with two powerful assumptions: one, state tort and contract actions are available without preemption by earlier federal legislation and two, following the 1986 Act's effect state law actions remain available. The 1987 Act expressly states these assumptions. Defendant's assertion that the statement, made in the purpose and summary section of the House Report on the 1986 Act, "[v]accine-injured persons . . . [who] reject a judgment and award made under the compensation program . . . may file a civil action for damages relating to a vaccine injury just as he or she may have done prior to the enactment of the legislation," is neutral on the issue of preemption strains a normal reading. H.R.Rep. No. 908, 99th Cong., 2d Sess. 4, *reprinted in* 1986 U.S. Code Cong. & Admin. News 6287, 6344-45.

Since Congress did not believe, in 1986 or 1987, that federal public health policies require preemption of state tort and contract law regarding vaccines it is dubious that the court should contemporaneously make the opposite policy determination. The point of time that is relevant in deciding whether a federal policy requires preemption, as opposed to point of time when the intent of a statute to preempt is discerned, is the time of the suit. *See Hillsborough*, 471 U.S. at 720-722, 722 n. 5, 105 S.Ct. at 2380 n. 5 (the Court considers contemporaneous policy interests).

2. *Whether Virginia law and its "learned intermediary" doctrine preclude recovery from a vaccine manufacturer*

Under Virginia law, recoveries for personal injuries caused by defective products can be made as breach of an implied warranty of merchantability or under a tort theory of negligent design. The warranty cause of action bears considerable similarity to the doctrine of strict liability in tort explained in Restatement (Second) of Torts § 402A, though Virginia has not adopted § 402A. *Lust v. Clark Equip. Co.*, 792 F.2d 436, 438-39 (4th Cir. 1986). The warranty cause of action has two elements: (1) the goods were "unreasonably dangerous" either for the use to which they would ordinarily be put or for some other reasonably forseeable purpose, and (2) the unreasonably dangerous condition existed when the goods left the manufacturer's control. *Bly v. Otis Elevator Co.*, 713 F.2d 1040, 1043 (4th Cir. 1983) (quoting *Logan v. Montgomery Ward & Co.*, 216 Va. 425, 428, 219 S.E.2d 685, 687 (1975)). A product is "unreasonably dangerous" if defective (1) in assembly or manufacture, (2) if imprudently designed, or (3) if not accompanied by adequate warnings about its hazardous properties. *Id.; Lust* 792 F.2d at 438.

Plaintiff claims that defendant's product is "unreasonably dangerous" thereby breaching the warranty of merchantability in two manners, one, by defective design, two, by inadequate warning. There is yet another claim, pleaded by plaintiff, and allowed under Virginia law, in tort for negligent design.

The two warranty theories muddle to some extent because plaintiff alleges that one aspect of the inadequacy of defendant's warning was its failure to disclose the defective design of the product. That allegation makes every defective design case a failure to warn case. But plaintiff does allege other defects of the warning, adequate to state a cause of action.

Defendant muddles the two theories in the other direction. It argues that an adequate warning precludes imposition of liability for a defective product on any theory. Thus, it argues that its adequate warning precludes the defective design claim based on warranty. Defendant has a threshold problem in making the argument here because defendant did not make it below. Defendant's warning arguments below dealt only with whether the warning was adequate as a matter of law to foreclose the failure to warn claim. Plaintiff argues that we, therefore, should not consider the argument. The question is close. The precise argument was not presented below but it is not a substantial shift in theory. Plaintiff's claim for breach of warranty alleges two manners in which the product was unreasonably dangerous. An argument that refutation of one theory of warranty recovery forecloses the other when the two are so closely related does not run afoul of fairness or the "sifting of issues" considerations embodied in the rule not to pass upon contentions not asserted in the district court.

When defendant's argument is considered, it fails. The cases it cites are not directly on point. The argument is based on a dictum in *Brockett v. Harrell Bros., Inc.*, 206 Va. 457, 143 S.E.2d 897 (1965). *Brockett* was an adulterated food case in which the court indicated that while contributory negligence does not apply to claims for breach of the implied warranty of wholesomeness of food, plaintiff cannot recover for defects known, visible or obvious to her. *Id.* at 463, 143 S.E.2d at 902. Defendant's argument extends this dictum to mean that plaintiff cannot recover in warranty for hazards that were adequately warned of. Virginia courts have not carried this dictum as to ordinary consumer products, like food, to all products.

The Supreme Court of Virginia in *Featherall v. Firestone Tire and Rubber Co.*, 219 Va. 949, 252 S.E.2d 358 (1975), considered many products liability issues includ-

ing claims for breach of implied warranty of merchantability by inadequate warning, breach of implied warranty of merchantability by improper design and tort negligent design of a tank lid. The court found that plaintiff could not recover on any of these three theories from the manufacturer of the tank lid. The court considered each claim independently, it did not, after concluding that no duty to warn arose, foreclose the warranty or tort negligence defect claims.

We have decided that federal law does not preempt plaintiff's state law causes of action and that under Virginia law, an adequate warning does not foreclose a design defect claim in either warranty or tort.

We now consider each of the state law tort claims: (a) failure to warn, a manner under which the product would be "unreasonably dangerous" and breach the implied warranty of merchantability, (b) defective design, a second manner in which the product would be unreasonably dangerous, and (c) negligent design, a tort action.

a. *Failure to warn*

A product can be unreasonably dangerous if not accompanied by adequate warnings about its hazardous properties. With prescription drugs, the duty is not the normal duty to warn the ultimate consumer. Rather, the duty is to warn the physician administering the drug. *Stanback v. Parke, Davis and Co.*, 657 F.2d 642, 644 (4th Cir. 1981) (applying Virginia law); *Pfizer, Inc. v. Jones*, 221 Va. 681, 684, 272 S.E.2d 43, 44 (1980). The trial court ruled that the warning given by defendant to plaintiff's physician was adequate as a matter of law, and formed a basis in addition to federal preemption to reject the failure to warn claim.

The adequacy of a warning is a question of fact for the jury. *Pfizer*, 221 Va. at 683-84, 272 S.E.2d at 44-45. The issue is whether the warning was reasonable. *Id.* Defendant and the trial court make much of the fact

that plaintiff's physician, Dr. Metzger, testified on deposition that the warning was "very adequate." Defendant argues, and the trial court held, that adequacy was thereby conclusively established.

We disagree on two grounds. First, Virginia law does not support the notion that the treating physician's subjective view as to adequacy conclusively determines that issue. In *Pfizer*, the Supreme Court of Virginia found a warning adequate as a matter of law in spite of the treating physician's testimony of inadequacy. Second, plaintiff alleges that the warning should have contained a statement about a difference, known to defendant at the time, in adverse reaction rates between different pertussis vaccines. Dr. Metzger testified that had he known that information he would have used the vaccine with the lowest reaction rate. Thus, the adequacy of the warning even in Dr. Metzger's view is in issue.

There is then a genuine issue regarding the adequacy of the warning. Summary judgment on the failure to warn claim was improper.

b. *Design Defect* and

c. *Negligent Design*

A product can be unreasonably dangerous if imprudently designed and such a finding will support a claim for breach of the implied warranty of merchantability. In addition, and separate from the warranty claim, is a tort claim for negligent design. *Featherall v. Firestone Tire and Rubber Co.*, 219 Va. 949, 961-65, 252 S.E.2d 358, 366-68 (1979). In the former the focus is on the product and its attributes, in the latter the focus is on the defendant's conduct.

The merits of the design defect claims were not addressed below, the trial court dismissed any design defect claim as preempted. Since we reverse the preemption ruling, the design defect claims move back into the case.

REVERSED.

WILKINS, Circuit Judge, concurring:

I agree with the majority, but for different reasons, that Congress did not intend to completely preempt state tort actions for DTP vaccine-related injuries. The majority reaches this conclusion without deciding what congressional intent is reflected in the National Childhood Vaccine Injury Act of 1986, 42 U.S.C.A. §§ 300aa-1, *et seq.* (West Supp. 1987). Prior to the passage of this Act, federal law appeared to preempt any state action alleging defective design of the DTP vaccine. But, this Act unmistakably demonstrates that Congress intended to preempt state law in only limited areas of this field. *See Grove City College v. Bell*, 465 U.S. 555, 567, 104 S.Ct. 1211, 1218, 79 L.Ed.2d 516 (1984) (evidence of congressional intent may be gleaned from subsequent actions).

In deciding whether federal law preempts state law, "our sole task is to ascertain the intent of Congress." *California Fed. Sav. & Loan Ass'n v. Guerra*, 479 U.S. ——, ——, 107 S.Ct. 683, 689, 93 L.Ed.2d 613, 623 (1987). In the absence of express congressional intent, preemption may be inferred to the extent that "the state law stands 'as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'" *Id.* (quoting *Hines v. Davidowitz*, 312 U.S. 52, 67, 61 S.Ct. 399, 404, 85 L.Ed. 581 (1941)). Although preemption should not be lightly presumed, *id.*, the legislative history of the Act presents some compelling reasons in support of a finding of preemption. H.R.Rep. No. 908, 99th Cong., 2d Sess. 1-7, *reprinted in* 1986 U.S. Code Cong. & Admin.News 6287, 6344-48 (Legislative History).

For many years, one of this nation's main public health priorities has been the prevention of childhood diseases by immunization. Through federal leadership and state immunization laws, most children are vaccinated against

the major childhood diseases prior to entering school. As a result, polio, diphtheria, and tetanus have been virtually eliminated in this country. While the immunization programs have been widely successful in preventing the deaths of thousands of children each year, a small but significant number of children have been injured from unavoidable side effects of some vaccines.

There is no "perfect" vaccine currently available on the market. Some vaccines have potentially fatal side effects, especially the pertussis component of the DTP vaccine. Notwithstanding the potential hazards, the medical community and parent groups have taken the position that the risk of contracting the diseases is greater than the possible side effects of immunization. The federal government continues to support immunization programs and in the majority of states, vaccination is still mandatory for school admission.

Injured children have sought compensation in the courts with increasing frequency. This has resulted in an increase in the price of vaccines, and a decrease in the level of immunization of certain diseases with a corresponding increase in the incidence of those diseases. As a further consequence of the increase in litigation, particularly regarding the DTP vaccine, manufacturers are reconsidering their future role in the vaccine market. Very few companies now manufacture childhood vaccines. American Cyanamid is one of the only two which manufactures the DTP vaccine. The withdrawal of any manufacturer from the market poses a serious threat to public health, in the form of vaccine shortages with resulting decreased immunization and a possible resurgence of these diseases.

Under these circumstances alone, preemption would be warranted because state tort actions for design and warning defects stand as an obstacle to a major federal purpose. However, read as a whole, the legislative his-

tory and the Act demonstrate that congressional intent was not to resolve these problems by complete preemption of state tort actions. Rather, Congress established a no-fault compensation system which in part preempts state law, but largely complements the state tort systems.

By requiring claimants to exhaust their administrative remedies in a speedy, no-fault system prior to filing court actions, Congress hoped to divert a significant number of potential litigants. Legislative History, *supra* at 6354. Children injured from vaccines administered after the effective date of the Act must proceed through the system as a prerequisite to filing a court action. 42 U.S.C.A. § 300aa-11. Those, such as Tracy Abbot, who were injured prior to the effective date are eligible to participate in the new system, but are not required to exhaust its remedies before resorting to the courts. *Id.* While the purpose of the system is to reduce litigation, the Act does not entirely preempt state laws.

The Act generally provides that "State law shall apply to a civil action brought for damages for a vaccine-related injury or death." 42 U.S.C.A. § 300aa-22(a). However, the Act does expressly preempt state law in several respects by: (1) adopting comment k of Section 402A of the Restatement of Torts (Second), precluding liability for damages arising from unavoidable side effects of a properly prepared vaccine accompanied by proper directions and warnings; (2) establishing a rebuttable presumption that warnings are adequate if they comply with federal regulations; and (3) codifying the learned-intermediary doctrine. 42 U.S.C.A. §§ 300aa-22(b), (c). Significantly, the Act also preempts state statutes which prohibit civil actions against manufacturers for vaccine-related injuries. 42 U.S.C.A. § 300aa-22(e); *see also* Legislative History, *supra* at 6368.

Finally, in the Vaccine Compensation Amendments of 1987, which set the effective date of October 1, 1988, Congress clearly expressed its intent:

> [A]t the time of original enactment and in passing this legislation, the Committee acted with the understanding that tort remedies were and are available....
>
> ....
>
> It is not the Committee's intention to preclude court actions under applicable law. The Committee's intent at the time of considering the Act and in these amendments was and is to leave otherwise applicable law unaffected, except as expressly altered by the Act and Amendments.

H.R.Rep. No. 391, 100th Cong., 1st Sess. 691 (1987), U.S.Code Cong. & Admin.News 1987, pp. 2313-1, 2313-365. Despite our differing analyses, we have reached the same conclusion: Congress did not intend to completely preempt state tort law in the area of vaccine-related injuries.

APPENDIX B

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
ALEXANDRIA DIVISION

Civil Action No. 86-857-A

TRACY ISABEL ABBOT, a minor who sues by her mother and next friend, Deborah Abbot,
Plaintiff,

v.

AMERICAN CYANAMID CO., a Maine Corporation,
Defendant.

MEMORANDUM OPINION IN SUPPORT OF ORDER OF FEBRUARY 9, 1987

This case came before the Court on defendant's F. R. Civ. P. 56 motion for summary judgment.

The complaint alleges that on or about August 9, 1983, the plaintiff, a five month old infant, was injected by Dr. Arthur Z. Metzger with the commonly known diphtheria-tetanus-pertussis (DTP) vaccine, also referred to as DPT and Tri-Immunol. As a result of this injection the plaintiff suffered and continues to suffer severe neurological damage. Plaintiff alleges that the defendant failed to develop a safer vaccine, failed to provide sufficient warnings that DTP contained impurities or toxins which could cause injury when injected, and breached its implied warranty of merchantability as DTP was not of merchantable quality for the ordinary use for which it was designed.

Defendant, in its motion, contends that Congress has delegated to FDA the authority to determine the safety and efficacy of vaccines used in the U.S. pursuant to 21 U.S.C. § 301 *et seq.*, and that such regulation preempts plaintiff's claims. That FDA's control over the design, manufacture, and approval of the warnings of DTP vaccine is pervasive and complete; the federal interest in vaccine regulation is dominant and calls for uniform national regulation; and that any jury decision disapproving the design, manufacture, or adequacy of the warnings of DTP vaccine would present a direct conflict with federal law and national policy. Defendant further states that the Congressional intent would be thwarted if state law were allowed to "supplement" the federal regulations governing DTP vaccine.

Plaintiff contends that if defendant had made a less than whole vaccine as other manufacturers and researchers have done and are now doing, defendant would have reduced substantially plaintiff's injury risk. That the 1986 National Childhood Vaccine Injury Act is a clear and unambiguous expression of Congress' intent to provide vaccine injury victims with a remedy under state common tort principles, and that if the Court does not find express preemption in the aforementioned 1986 Act's clear and unambiguous language, plaintiff may still bring a state tort action because defendant failed to satisfy any of the tests for implied preemption.

The plaintiff makes no claim that this particular quantity of vaccine was not made in conformity with FDA standards, nor that it was adulterated or contaminated in any way.

The preemption doctrine is based fundamentally on Art. 6, Clause 2 of the U. S. Constitution. Express and implied preemption have emerged from federal jurisprudence. Depending on the statutory scheme, federal law may expressly preempt state law. *Pacific Gas & Electric*

Co., v. State Energy Resources Conservation and Development Commission, 461 U.S. 190, 103 S. Ct. 1713, 75 L. Ed.2d 752 (1983), *Jones v. Rath Packing Co.*, 430 U.S. 519, 525, 97 S.Ct. 1305, 1309, 51 L. Ed.2d 604 (1977); *see also, Cippollone v. Liggett Group, Inc.*, 789 F.2d 181 (3d Cir. 1986). State common law, statutes, and regulations are subject to preemption. *See San Diego Building Trades Council v. Garmon*, 359 U.S. 236, 247, 79 S. Ct. 773, 780, 3 L. Ed.2d 775 (1959). State common law can be preempted by federal regulation as well as by federal statutes. *Hillsborough County, Florida v. Automated Medical Laboratories, Inc.*, 471 U.S. 707, 105 S. Ct. 2371, 85 L. Ed.2d 714 (1985).

In the absence of express preemption, federal case law has established four factors which must be analyzed in determining whether Congress intended to impliedly preempt or occupy a particular field of law:

> (1) The aim and intent of Congress as revealed by the statute itself and its legislative history . . .;
>
> (2) The pervasiveness of the federal regulatory scheme as authorized and directed by the legislation and as carried into effect by the federal administrative agency . . .;
>
> (3) The nature of the subject matter regulated and whether it is one which demands "exclusive federal regulation in order to achieve uniformity vital to national interests" . . .; and ultimately
>
> (4) "Whether, under the circumstances of (a) particular case, (state) law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress."

Northern States Power Co. v. State of Minnesota, 447 F.2d 1143, 1146-1147 (8th Cir. 1971), *aff'd*, 405 U.S. 1035, 92 S.Ct. 1307, 31 L. Ed.2d 576 (1972). *KVUE, Inc. v. Austin Broadcasting Corp.*, 709 F.2d 922, 931-32

(5th Cir. 1983), *aff'd sub nom, Texas v. KVUE, Inc.* 465 U.S. 1092 (1984), states:

> The test of preemption is whether (1) the area requires national uniformity, (2) there is evidence of Congressional design to preempt the field, *or* (3) the state statute actually and directly conflicts with the federal.

A similar set of facts were presented in the recent Texas decision in *Hurley et al v. Lederle Laboratories*, No. 85 Civ. 449 (E.D. Texas December 31, 1986). As in the present case, after plaintiff's child was immunized against diphtheria, tetanus, and pertussis with defendant's manufactured DTP vaccine, the child sustained severe and irreversible neurological damage. The *Hurley* court ruled that federal law preempts plaintiff's claims of defective design, inadequate labeling/warning, and punitive damages, and defendants were entitled to summary judgment as a matter of law on these claims.

Unquestionably, the FDA does have authority to promulgate regulations pursuant to 21 U.S.C. § 371(a) which are binding as law. The courts acknowledge FDA's authority to promulgate regulations concerning the safety and design of drugs within the U.S. Under 21 U.S.C. § 321, the ultimate determination of safety of a drug is not a matter given to the courts, but one to be determined by the Food & Drug Administration upon submission of a new drug application. *U.S. v. 1,048,000 Capsules* (Afrodex), 494 F.2d 1158, 1160 (5th Cir. 1974).

This Court must decide whether federal law preempts a judicial determination that DTP could be held defective in both production method and in design. The comprehensive and pervasive nature of the Food, Drug and Cosmetic Act (FDCA), the Public Health Services Act (PHSA), and their respective regulations evidence preemptive intent so strong that it precludes any state law determination that DTP is defectively designed. The

FDA has promulgated exhaustive rules and regulations concerning the licensing, testing, production, distribution, review, and approval of all biological DTP vaccines. *See generally*, 21 C.F.R. §§ 211, 312, and 600, *et seq.* Each DTP manufacturer must be licensed and submit detailed descriptions to the FDA which define the DTP vaccine manufacturing process. Methods, and strict personnel qualifications, investigations, inspections of facilities, testing, and reporting on "new designs or new types" of DTP vaccines are prescribed by FDA.

There are dominant, overriding federal interests in promoting uniformity in the design and manufacture of DTP vaccines. As evidence of FDA's intent to promote uniformity in the design of DTP, all but nine of 52 jurisdictions (50 states, District of Columbia and Puerto Rico), require DTP vaccine (with "whole cell" pertussis component) as part of their public health immunization programs which are federally funded and sponsored. The "whole cell" DTP vaccine remains the only DTP vaccine presently licensed by the FDA, further evidencing an intent to keep the DTP design uniform nationwide.

A state common law determination that DTP design and manufacture is defective will gravely and irreconcilably conflict with the federal regulatory scheme and the national policies of immunization, adequate production, and supply of DTP. In effect, it will chill the efforts of the federal government to ensure that all U. S. children are immunized and frustrate Congress' intent in fostering such programs.

The FDA has determined the manufacturing process employed by defendants and the "whole cell" DTP "state of the art" design to be safe and effective for the purpose for which it is designed. 50 *Fed. Reg.* 51,104 (1985); 50 *Fed. Reg.* 51,055 (1985). No other DTP design has been adequately demonstrated to be both safer than and as effective as the "whole cell" DTP vaccine manufac-

tured and marketed by defendants. Were the defendant to do the testing and development plaintiff suggests it should have done, it could not have sold the product or used it as a replacement for the present vaccine. The FDA has refused to relicense any fractionated cell product, and the manufacture and sale of such a vaccine would constitute a criminal offense under the FDCA. *See* 21 U.S.C. 331(d), 333(a), 355(a) (1982), *Toner v. Lederle Laboratories*, 779 F.2d 1429, 1431 (9th Cir. 1986).

There is no express preemption language in the federal statutes or any relevant legislative history indicating Congressional intent to preempt state regulation of DTP labeling or design in the FDCA or the PHSA. However, the comprehensive nature of FDA regulations, including certain mandatory product inserts,[1] evidences preemptive intent to establish implied preemption as to the labeling/warning of DTP in the present case.

The nature of DTP labeling relegates exclusive federal regulation to achieve uniformity crucial to national interests. Drug labeling is an area where national uniformity should be promoted and constitutes a dominant federal interest. 50 *Fed. Reg.* 51,403 (1985), *Cosmetic, Toiletry and Fragrance Association, Inc. v. State of Minnesota*, 440 F. Supp. 1216, 1220 (D. Minn. 1977), *aff'd*, 575 F.2d 1256 (8th Cir. 1978).

Any state regulation or judicial restriction of labeling/warning would conflict with the federal statutory and regulatory scheme in this area. *See generally, Hines*

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[1] For a product insert accompanying the DTP vaccine, as well as any pharmaceutical product distributed in the U.S., certain information must be provided such as:

> (1) The composition of the product, (2) The product's administration schedule, (3) When the product's usage is indicated and contraindicated, (4) The product's potential adverse reactions which have been associated with the product's use. 21 U.S.C. §§ 610.60-610.65.

v. Davidowitz, 312 U.S. 52, 67-68 (1941); *Pacific Gas & Electric Co.*, 461 U.S. at 220. FDA's intent and policy in the regulation of labeling/warning of DTP is to promote uniformity in this particular area and to insure that a complete and accurate explanation of the drug is provided to the medical community. 44 *Fed. Reg.* 37,441 (1979). The plaintiff's claim of inadequate warning is preempted by federal law.

In addition to the federal preemption, the plaintiff's claim as to inadequate warning would fail because there is only a duty to adequately warn the prescribing physician.

In *Reyes v. Wyeth Laboratories*, 498 F.2d 1264, 1276 (5th Cir. 1974), the Court of Appeals explained the rationale of the learned intermediary doctrine:

> Prescription drugs are likely to be complex medicines, esoteric in formula and varied in effect. As a medical expert, the prescribing physician can take into account the propensities of the drug, as well as the susceptibilities of his patient. His is the task of weighing the benefits of any medication against its potential dangers. The choice he makes is an informed one, an individualized medical judgment bottomed on the knowledge of both patient and palliative. Pharmaceutical companies then, who must warn ultimate purchasers of dangers inherent in patent drugs sold over the counter, in selling prescription drugs are required to warn only the prescribing physician, who acts as a "learned intermediary" between manufacturer and consumer.

The recent holding in *Smith v. Wyeth Laboratories, Inc.*, No. 84 Civ. 2002 (S.D.W.Va. August 21, 1986) supports the ruling in *Reyes*.

The only exception to the Learned Intermediary Doctrine appears to be in a clinic-like setting where a non-

physician such as a nurse or other health care personnel administers, e.g. polio vaccine, as part of a mass immunization program. Where no individualized medical judgment intervenes between the manufacturer of a prescription drug and the ultimate consumer, it is the responsibility of the manufacturer to see that warnings reach the consumer. *David v. Wyeth Laboratories*, 399 F.2d 121 (9th Cir. 1968). This exception would not apply in this case as the vaccine was administered by a physician.

Not only does the Learned Intermediary Doctrine dispose of the duty to warn issue, the plaintiff's own physician supports the adequacy of the warning. Dr. Metzger who administered the vaccine testified in deposition that the warning was adequate. (Metzger Deposition p. 121). Thus, defendant has met its duty to warn as a matter of law.

For the reasons stated, I find that this area is preempted. DTP is an integral part of the U. S. national health policy to immunize children against diphtheria, tetanus, and pertussis. The FDA has comprehensively set out DTP vaccine design regulations and has specifically rejected some of the designs which plaintiff desires to have implemented. The DTP vaccine must be made within the FDA parameters as promulgated in C.F.R. 211, 312, and 600, *et seq.* Since Congress has impliedly delegated to the FDA authority to determine the safety and efficacy of vaccines used in the U. S. pursuant to 21 U.S.C. § 301 *et seq.*, defendant's motion for summary judgment is granted.

/s/ Claude M. Hilton
CLAUDE M. HILTON
United States District Judge

Alexandria, Virginia
Date: Mar. 9, 1987

APPENDIX C

UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

No. 87-1578

TRACY ISABEL ABBOT, ETC.,
Plaintiff-Appellant,

v.

AMERICAN CYANAMID CO., ETC.,
Defendant-Appellee,

PHARMACEUTICAL MANUFACTURERS ASSOCIATION, *et al.*,
Amici Curiae.

On Petition for Rehearing With Suggestion for Rehearing In Banc

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[Filed May 25, 1988]

The appellee's petition for rehearing and suggestion for rehearing in banc were submitted to this Court. As no member of this Court or the panel requested a poll on the suggestion for rehearing in banc, and

As the panel considered the petition for rehearing and is of the opinion that it should be denied,

IT IS ORDERED that the petition for rehearing and suggestion for rehearing in banc are denied.

APPENDIX D

42 U.S.C. § 262 Regulation of biological products

(a) No person shall sell, barter, or exchange, or offer for sale, barter, or exchange in the District of Columbia, or send, carry, or bring for sale, barter, or exchange from any State or possession into any other State or possession or into any foreign country, or from any foreign country into any State or possession, any virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product, or arsphenamine or its derivatives (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of diseases or injuries of man, unless (1) such virus, serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or other product has been propagated or manufactured and prepared at an establishment holding an unsuspended and unrevoked license, issued by the Secretary as hereinafter authorized, to propagate or manufacture, and prepare such virus, serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or other product for sale in the District of Columbia, or for sending, bringing, or carrying from place to place aforesaid; . . . .

* * * *

(d) Licenses for the maintenance of establishments for the propagation or manufacture and preparation of products described in subsection (a) of this section may be issued only upon a showing that the establishment and the products for which a license is desired meet standards, designed to insure the continued safety, purity, and potency of such products, prescribed in regulations, and licenses for new products may be issued only upon a showing that they meet such standards. All such licenses shall be issued, suspended, and revoked as prescribed by regulations and all licenses issued for the maintenance

of establishments for the propagation or manufacture and preparation, in any foreign country, of any such products for sale, barter, or exchange in any State or possession shall be issued upon condition that the licensees will permit the inspection of their establishments in accordance with subsection (c) of this section.

* * * *

(f) Any person who shall violate, or aid or abet in violating, any of the provisions of this section shall be punished upon conviction by a fine not exceeding $500 or by imprisonment not exceeding one year, or by both such fine and imprisonment, in the discretion of the court.

APPENDIX E

42 U.S.C.A. § 300aa-1 Establishment

The Secretary shall establish in the Department of Health and Human Services a National Vaccine Program to achieve optimal prevention of human infectious diseases through immunization and to achieve optimal prevention against adverse reactions to vaccines. The Program shall be administered by a Director selected by the Secretary.

§ 300aa-2 Program responsibilities

(a) The Director of the Program shall have the following responsibilities:

(1) Vaccine research

The Director of the Program shall, through the plan issued under section 300aa-3 of this title, coordinate and provide direction for research carried out in or through the National Institutes of Health, the Centers for Disease Control, the Office of Biologics Research and Review of the Food and Drug Administration, the Department of Defense, and the Agency for International Development on means to induce human immunity against naturally occurring infectious diseases and to prevent adverse reactions to vaccines.

(2) Vaccine development

The Director of the Program shall, through the plan issued under section 300aa-3 of this title, coordinate and provide direction for activities carried out in or through the National Institutes of Health, the Office of Biologics Research and Review of the Food and Drug Administration, the Department of Defense, and the Agency for International Develop-

ment to develop the techniques needed to produce safe and effective vaccines.

* * * *

(5) Production and procurement of vaccines

The Director of the Program shall, through the plan issued under section 300aa-3 of this title, ensure that the governmental and non-governmental production and procurement of safe and effective vaccines by the Public Health Service, the Department of Defense, and the Agency for International Development meet the needs of the United States population and fulfill commitments of the United States to prevent human infectious diseases in other countries.

(6) Distribution and use of vaccines

The Director of the Program shall, through the plan issued under section 300aa-3 of this title, coordinate and provide direction to the Centers for Disease Control and assistance to States, localities, and health practitioners in the distribution and use of vaccines, including efforts to encourage public acceptance of immunizations and to make health practitioners and the public aware of potential adverse reactions and contraindications to vaccines.

* * * *

§ 300aa-22. Standards of responsibility

(a) General rule

Except as provided in subsections (b), (c), and (e) of this section State law shall apply to a civil action brought for damages for a vaccine-related injury or death.

(b) Unavoidable adverse side effects; warnings

(1) No vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after the effective date of this subpart if the injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings.

APPENDIX F

EXCERPT FROM JANUARY 30, 1987 HEARING ON SUMMARY JUDGMENT MOTION

* * * *

[22] THE COURT: But they couldn't have manufactured and distributed that new vaccine which you allege is better without submitting that to the FDA and getting FDA approval.

MR. PREISER [Counsel for Respondent]: They submit their vaccine to the FDA every time they send it out. If there were less endotoxins in it, if it were less likely to cause reactions, I don't think it is the FDA's position and I don't think it is the Court's position that they would have said, come give us the more reactive vaccine, give us the one with the more foreign products in it. I think that the equivalent methods section of 21 C.F.R. says that.

Moreover, in some of the other sections it says can you make this by different means, you can heat it differently, you can detoxify it differently, you can do this differently, you can do that differently. Yes, they had the approval of the FDA for the minimum requirements on their product. There were 21 other products.

THE COURT: Well, you know, you say the minimum [23] requirements on the product. I don't interpret that to be the case. And you tell me if I am wrong, because if they want to do more than the minimum, they have to go gack to FDA and get approval to do more than the minimum, as you would describe it. So, actually we are not dealing with minimums and maximums in terms of selling this particular product. They can only sell that product one way.

MR. PREISER: An example, if I may. They could have taken a less toxic strain of the pertussis isolate they used to make the vaccine and grown their product from the less toxic strain that was still antigenic, giving the

protective factor that was necessary, passed all the FDA tests and still had a better product, wouldn't have had to change a thing.

THE COURT: And you have got evidence—

MR. PREISER: They could have detoxified it differently or heated it differently and still satisfied the FDA requirements.

THE COURT: And you have got evidence that they could have used a different strain, and that because of that that's what caused this injury?

MR. PREISER: We have got evidence to show that there are a number of ways they could have made a less toxic and yet antigenic vaccine and still complied with the FDA requirements. And moreover, I suggest to the Court that if they submitted a different vaccine and that vaccine was better, which they had [24] the capability of making, the FDA would have approved it.

THE COURT: All right. What do you say to the argument that they have evidence that you could have used your process differently or developed a portion of this strain in a less toxic—

MR. ROBERTSON [Counsel for Petitioner]: I don't think they do, Your Honor. It is certainly not any part of their, it is certainly not any one of their designated exhibits in the trial. They have never even taken any discovery in the case about the actual lot and batch of this particular case. That was an afterthought motion they made after the discovery was closed for lot and batch information. We didn't, no way we could get it in time. That motion was overruled. This case still has nothing to do with the specific vaccine that was administered to this child.

The Court is exactly right about the, about what they would have had to do. If Lederle had done what the plaintiff wanted them to do, which is to apply to the FDA for a different kind, to do a different kind of vaccine, the FDA, and it is all spelled out very plainly in this document that is before the Court, particularly at

page 51043, if the Court wants to look that up, and 51045, the FDA would have required them to conduct significant, extensive, complicated field trials to demonstrate the efficacy and the safety of the new vaccine before they could market it.

Now, as to the strains, as to the business of the [25] strains of the vaccine. Again, there is nothing in this case about the exact method of manufacture or strains used in this lot of vaccine. It is a generic case, we don't like what the FDA says.

THE COURT: All right. Well, I am going to do this with this motion. I am going to continue the case for one week. And I would like for the plaintiff to file something with me that deals solely with what evidence is in this case that would go to the question of whether or not there could have been a different, a less toxic culture used, and forgive my terminology if it is inaccurate, or the question of heating this particular vaccine.

* * * *

APPENDIX G

EXCERPT FROM RESPONDENT'S SUPPLEMENTAL BRIEF IN OPPOSITION TO DEFENDANT'S MOTION FOR SUMMARY JUDGMENT

Plaintiff has been offered the opportunity to present evidence which supports theories of her case based upon issues other than design defect and failure to warn. After a review of the facts and circumstances of this case and the evidence accumulated through the discovery process herein and in consideration of the law of the State of Virginia, she offers no evidence to support such other theories.

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APPENDIX H

IN THE UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

No. 87-1578

TRACY ISABEL ABBOT,
Plaintiff-Appellant,

v.

AMERICAN CYANAMID CO.,
Defendant-Appellee.

On Appeal from the United States District Court
for the Eastern District of Virginia

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE

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AUGUST 1987

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IN THE UNITED STATES COURT OF APPEALS
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No. 87-1578

TRACY ISABEL ABBOT,
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On Appeal from the United States District Court
for the Eastern District of Virginia

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE

INTEREST OF THE UNITED STATES

The United States submits this *amicus curiae* brief on behalf of the Department of Health and Human Services (HHS), which maintains a longstanding national program to vaccinate all American children against pertussis, or "whooping cough." The purpose of this brief is to provide the Court with background information concerning the federal government's role in pertussis vaccination. The United States expresses no opinion on the question whether federal law preempts plaintiff's state tort remedies in this case.

INTRODUCTION

Federal public health authorities, including the Food and Drug Administration (FDA), the Centers for Disease Control (CDC), the National Institutes of Health (NIH), and other agencies, have, for almost forty years, promoted vaccination of the populace with diptheria-tetanus-pertussis (DTP) vaccines containing as one of their three components the so-called "whole cell" pertussis vaccine.[1] These agencies have supported use of this "whole cell" component because of its proven value for millions of children, even though they recognize that it may have serious adverse side effects for a small number of those vaccinated. These agencies are unaware of any other pertussis vaccine produced in the world today that has been adequately demonstrated to be both safer than and as effective as the "whole cell" vaccine licensed for sale by the FDA.

Pertussis is a serious disease which is most dangerous to its youngest victims. Before the introduction of the "whole cell" vaccine, pertussis disabled and killed thousands of children annually in the United States. After more than 40 years of widespread use of that vaccine in this country, the disease has been brought largely under control. Pertussis remains a leading cause of infant deaths, however, in some other parts of the world which lack such vaccination programs.[2] Moreover, the bacterium causing the disease persists even where the disease is under control, as in this country. This leads to the probability of epidemics whenever the use of the vaccine declines significantly. The responsible federal health

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[1] Such a three-component vaccine was first licensed by the predecessor to FDA's Office of Biologics Research and Review in 1949.

[2] See 50 Fed. Reg. 51040-42 (1985) (report of the Panel on Review of Bacterial Vaccines and Toxoids). This report, by a group of non-government medical experts appointed by FDA to review the safety, efficacy and labeling of all bacterial vaccines, contains a thorough discussion of the disease, the development of the "whole cell" vaccine, and the vaccine's safety and efficacy.

agencies have consistently recommended that all children, excepting those with specific medical contraindications, be inoculated.

In this case, plaintiff Tracy Isabel Abbot sued American Cyanamid Company, whose subsidiary, Lederle Laboratories, manufactures a "whole cell" pertussis vaccine. The plaintiff asserted that she suffered permanent brain damage as a result of being inoculated when she was five months old with Lederle's FDA-licensed DTP vaccine. The three-count complaint specifically alleged strict liability, breach of implied warranty of merchantability, and negligence. In response to the defendant's motion for summary judgment, the plaintiff made clear that her case was based on the contentions that Lederle's "whole cell" vaccine was defectively designed and that warnings accompanying the product were inadequate. Brief For Plaintiff-Appellant at 3-5.

The "whole cell" pertussis vaccine is made from whole killed cells of *Bordetella pertussis*, the bacterial agent that causes the disease. The vaccine contains substances which may be able to cause adverse reactions in vaccinees. The plaintiff here contended that Lederle could have and should have manufactured and sold a different type of pertussis vaccine less likely to cause adverse reactions. The district court granted summary judgment for the defendant on the ground that the plaintiff's tort claims against the manufacturer were preempted by the comprehensive and pervasive federal regulation of vaccines.[3]

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[3] With respect to the inadequate warning claim, the district court alternatively based its grant of summary judgment on the "learned intermediary doctrine" (*i.e.*, where a physician exercising individualized medical judgment is interposed between the manufacturer of a prescription drug and the patient, the manufacturer's duty to warn is satisfied by adequate warning to the physician). On the basis of deposition testimony by the physician who administered the Lederle vaccine to Tracy Abbot that he considered the warnings accompanying the product to be adequate, the court concluded as a matter of law that the defendant had met its duty to warn.

DISCUSSION

HHS supports the continuing manufacture and marketing of the "whole cell" vaccine because no alternative formulation has been adequately proven to be both safer than and as effective as the "whole cell" vaccine. HHS's support for continued production of this product is consistent with the vigorous recommendations of all sectors of the medical community, both public and private, which have carefully analyzed the dangers of the disease and the benefits and risks associated with the vaccine.

Experts still have not determined what part of the whole *B. pertussis* cell used in the "whole cell" vaccine provides immunity to the recipient. HHS, the governments of other nations, and numerous private firms like Lederle are all actively seeking a vaccine that provides all of the protection of the "whole cell" design without the attendant adverse clinical reactions. Until the time that HHS is convinced that such an alternative vaccine has been found, it will continue to advocate the use of "whole cell" vaccine as a vital part of our nation's public health policy.

1. *History and Epidemiology of Pertussis.*

Pertussis, or whooping cough, is a highly contagious disease caused by *Bordetella pertussis*, a bacterium. Human beings are the only natural hosts of *B. pertussis*, and infected individuals are the primary sources of disease in susceptible persons. Transmission occurs via droplets from the respiratory tract which are expelled into the air by infected individuals. Up to 90% of non-immune household contacts acquire the disease. *Report of the Committee on Infectious Diseases*, American Academy of Pediatrics (1986) ("The Red Book"). Later stages of the disease are characterized by severe and paroxysmal coughing which ends in a prolonged, high-pitched crow (the whoop) that is occasionally accompanied by vomiting. Recovery may take many weeks or

months. The disease is most dangerous to infants and young children. During the years 1940-1948, the mean annual pertussis mortality rate for infants up to 12 months of age was 64 per 100,000 population, as compared with only 6.4 per 100,000 children ages 1 through 4, and 0.2 for children ages 5 through 14. Cherry, "The Epidemiology of Pertussis and Pertussis Immunization in the United Kingdom and the United States: A Comparative Study," *Current Problems in Pediatrics* (1983) ("Cherry"), p. 18. Complications of pertussis include brain diseases, convulsions, partial lung collapse, secondary infections such as pneumonia, and permanent developmental retardation. See generally Manclark & Cowell, "Pertussis" in Germanier (ed.), *Bacterial Vaccines* (1984) ("Manclark & Cowell"), pp. 69-106.

In 1934, when this country suffered its worst pertussis epidemic, there were 265,000 reported cases of pertussis and 7,500 related deaths. Hinman and Koplan, *Pertussis and Pertussis Vaccine: Reanalysis of Benefits, Risks, and Costs*, Journal of the American Medical Association ("JAMA") (June 15, 1984). By the early 1940s, pertussis was responsible for two and half times the number of deaths as all of the following diseases combined: measles, mumps, rubella, diptheria, polio, meningitis, chicken pox, and scarlet fever. While the use of pertussis vaccine has reduced the number of deaths attributable to pertussis to approximately 10 per year ("Recommendation of the Immunization Practices Advisory Committee" ("ACIP"), *Morbidity and Mortality Weekly Report*, ("MMWR") U.S. Dept. of H.H.S., July 12, 1985), the potential for epidemics is still present, JAMA, p. 3113.

2. *Development of the Whole Cell Pertussis Vaccine.*

B. pertussis was identified as the cause of whooping cough in 1906 at the Brussels Pasteur Institute. The first vaccine against pertussis was licensed by the federal government in 1914. Work began on the develop-

ment of the forerunners of the current "whole cell" vaccines in the 1920s. This research led to the development of experimental vaccines and clinical trials in the 1930s. In the early 1940s, pertussis vaccination became widespread, and, in 1944, the Council on Pharmacy and Chemistry of the American Medical Association (AMA) accepted and endorsed pertussis vaccination. From 1943 to 1976 the country showed a 99% reduction in the reported cases of pertussis per 100,000 population, and an even more dramatic reduction in the number of deaths. Both the number of cases and deaths due to pertussis have remained constant since 1976. Cherry, pp. 11-12. CDC believes that, since 1980, 95 percent of all American children who have reached five years of age have received the complete course of immunization against pertussis.

In 1949, federal criteria governing the manufacturing process and potency testing of all batches of pertussis vaccine were developed. The same year the federal government licensed a combined product consisting of diphtheria and tetanus toxoids and "whole cell" pertussis vaccine and approved the product's labeling as well.[4] This type of product is the familiar diphtheria-tetanus-pertussis (DTP) vaccine produced by Lederle and two other licensed domestic commercial manufacturers today.

According to the best information available to the government, of the ten companies that have at any time obtained licenses to manufacture or distribute DTP vaccine in this country, only three, Lederle, Wyeth Laboratories, Inc., and Connaught, Inc., continue to produce the vaccine.[5] They were also the only manufacturers or dis-

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[4] This labeling has been revised and updated as experience with the vaccine has increased. FDA specifically approved the labeling (known as the "package insert") accompanying the Lederle product in this case, finding it both accurate and adequate.

[5] Lederle and Connaught market their DTP products. Wyeth no longer markets its DTP vaccine, we understand, but does manufac-

tributors in 1983, when Tracy Abbot received her inoculations. The pertussis vaccine used by all three firms, then and now, is of the "whole cell" type.[6]

It is well recognized that the "whole cell" pertussis vaccine is associated with rare, serious adverse reactions. However, clinical trials, 50 years of experience with the vaccine, and the great reduction in the number of reported cases of the disease and related deaths all demonstrate that, used properly, the "whole cell" pertussis vaccine is acceptably safe and very effective in controlling the disease. Manclark & Cowell, p. 84.[7]

The importance of inoculating children with "whole cell" vaccine is perhaps best demonstrated by reviewing what happened in the United Kingdom and Japan during the 1970s when the use of the vaccine declined. Because of public concern regarding the "whole cell" pertussis vaccine, the number of individuals immunized against pertussis in Britain dropped from 79 percent in 1973 to

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ture the vaccine which is then distributed by Lederle. SCLAVO, an Italian pharmaceutical firm, is licensed to manufacture and sell "whole cell" DTP vaccine in the United States but is not presently distributing its vaccine in this country.

[6] The Michigan and Massachusetts state health laboratories also have licenses from FDA to produce DTP vaccines for use in their respective states. Those vaccines also incorporate the "whole cell" pertussis component.

[7] In a very recent decision, an Ohio appellate court essentially agreed with this conclusion. *White* v. *Wyeth Laboratories*, Nos. 52108 and 52564, slip op. at 13 (Court of Appeals of Ohio, Eighth District, July 30, 1987). The *White* court held that Wyeth's DTP vaccine containing a "whole cell" pertussis component was an "unavoidably unsafe product" because it was "an apparently useful and desirable product, attended with a known but apparently reasonable risk." *Id.* The court concluded that "[p]ublic policy requires that the mere manufacture of the vaccine not be actionable on design defect grounds" and that the manufacturer was not liable for adverse reactions associated with the vaccine if adequate warnings of the risks were provided. *Id.*

31 percent in 1978. An epidemic of pertussis broke out between 1977 and 1980 that resulted in 102,500 cases of disease and 36 related deaths. In the winter of 1981-1982, approximately 1,400 cases of pertussis were reported each week to British public health officials. A total of 49,543 cases were reported during the first nine months of 1982 alone. Cherry, pp. 36-39 and MMWR (December 3, 1982), p. 629. The Japanese had a similar experience when the use of the "whole cell" vaccine declined from approximately 70 percent in the early 1970s to approximately 30 or 40 percent in 1975. By 1979, the Japanese reported an epidemic of 13,105 cases of pertussis and 41 deaths. Manclark & Cowell, p. 94, and U.S. Department of Health and Human Services, "Pertussis and Pertussis Vaccines in Japan", May 9, 1986. CDC estimates that, under current conditions, if the use of "whole cell" pertussis vaccine were halted in this country, there would be 353,000 additional cases of disease and 450 deaths per year. JAMA, p. 3112.

3. *Other Vaccines.*

It is the plaintiff's theory in this case that Lederle should be held liable because a design defect in the "whole cell" vaccine made it unreasonably dangerous. According to the plaintiff, two other types of vaccines are as effective as the "whole cell" vaccine and are safer in that they cause fewer adverse reactions. See Brief For Plaintiff-Appellant at 4 and n.4. The plaintiff argued that Lederle, instead of manufacturing a "whole cell" vaccine, should have developed, obtained FDA license approval for, and marketed in 1983 either an extracted cell or an acellular vaccine. *Id.* HHS is unconvinced that current evidence demonstrates that there are presently safer and equally effective alternatives to the "whole cell" vaccine.

(a) *Extracted Vaccines.* Eli Lilly and Company manufactured and marketed a DTP product called "Tri-

Solgen" between 1962 and 1977 under an FDA-approved license. "Tri-Solgen" contained a pertussis vaccine component prepared from an extract of whole *B. pertussis* cells that was a complex mixture which differed from whole cells primarily by being soluble. The extracted pertussis component of "Tri-Solgen" passed the same laboratory tests for freedom from toxicity and for potency required for "whole cell" vaccines. The extrated vaccine was considered effective based upon the fact that it met the laboratory requirements for potency. However, no controlled clinical efficacy trials were ever performed on this vaccine comparable to those performed on "whole cell" vaccine in the 1940s and 1950s.

Following the decision by Eli Lilly to cease manufacture of "Tri-Solgen", Wyeth Laboratories, Inc., which was then producing a "whole cell" vaccine, took an option from Eli Lilly to produce a "Tri-Solgen"-type extracted pertussis vaccine. After considerable research, Wyeth produced its own extracted vaccine in the late 1970s and, in 1982, submitted a license application to the FDA to manufacture and sell a DTP vaccine containing such a pertussis component. The license application included research information, production data, and two small clinical trials evaluating immuniogenicity (*i.e.*, capacity to confer immunity), as measured by antibody responses in children, and safety, as measured by adverse reaction information from all subjects tested. While there appeared to be fewer local and mild systemic reactions to the extracted vaccine than with "whole cell" vaccine, there were two severe reactions during the clinical tests—one episode of collapse and one episode of cyanosis—in the group receiving the extracted vaccine.

Wyeth's data were reviewed by FDA and by a panel of consultants convened by FDA. Based on the observation of the two serious reactions in children receiving the extracted vaccine and the fact that Wyeth's extracted vaccine had less potency than "whole cell" vaccine, they con-

cluded that additional data would be necessary before a license could be issued.[8] While technically the application has not been withdrawn, it has remained inactive and no license has been issued for Wyeth's extracted vaccine. In 1985, Eli Lilly voluntarily requested FDA to revoke its license to manufacture "Tri-Solgen," and the agency accordingly granted Lilly's request.

(b) *Acellular vaccines.* Acellular pertussis vaccines differ from earlier vaccines in that they contain less endotoxin (a toxic substance produced by the pertussis bacterium). While the acellular vaccines, which are marketed by Japanese firms, have been reported to be safer in some respects than the "whole cell" products, it is not clear whether they are as effective. Since 1981, the acellular vaccines have been used in the mass immunization program in Japan. Although the results with these vaccines are encouraging, additional clinical trials are in progress to demonstrate safety and efficacy. One of the clinical trials being watched with great interest is presently underway in Sweden. Changes made in the Swedish "whole cell" vaccine in the 1970s rendered that vaccine ineffective and its use was discontinued. As a result, Sweden has experienced a significant increase in the number of cases of pertussis in the years since 1974. The present clinical trial of two Japanese acellular vac-

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[8] Because the performance characteristics of biological products depend on the manufacturer, the manufacturing process, the manufacturing facility, and other variables, vaccines made by different manufacturers are treated as separate products, even if they are of the same design and for the same purpose. Therefore, Wyeth could not simply make and sell "Tri-Solgen"; rather, Wyeth had to obtain the manufacturing technology from Lilly and develop its own extracted pertussis vaccine. Wyeth's vaccine was then subject to FDA evaluation without regard to the existing approval of Lilly's similar extracted pertussis vaccine. Although the Wyeth vaccine was not approved, it is not possible to conclude that "Tri-Solgen" was "better" than the Wyeth vaccine because different tests were done on the two vaccines.

cines was designed by Swedish public health officials in close consultation with their American counterparts at FDA, NIH, and CDC, and the trial is being primarily funded by HHS. Neither of the two vaccines currently being tested in Sweden is licensed for use in the United States, and only one is approved for use in Japan.

Some early information is now available concerning the Swedish clinical trial. The study was designed as a classical randomized, double-blind, placebo-controlled trial.[9] Sweden could be used as the location for this type of study for several reasons: there is a relatively high incidence of pertussis among Swedish children, the country's medical care system is advanced and equipped to handle the extensive follow-up and record keeping functions such a study requires, and the Swedish health authorities do not recommend immunization against pertussis. Thus, investigators could ethically withhold both a vaccine known to be effective and acceptably safe (the "whole cell" vaccine) and a potentially useful experimental vaccine (acellular vaccines), and give a placebo instead. By comparison, HHS believes that it would be extraordinarily difficult to conduct such a study in the United States because there are so few cases of pertussis that it would take a trial including approximately 200,000 children to show any differences in safety or efficacy between the "whole cell" and acellular vaccines.

A total of 3,800 children, who were between the ages of six and nine months at the time of their first dose of vaccine, participated in the study in Sweden. All of the

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[9] In other words, in this trial the study population was randomly divided into three groups that were then given either of the two vaccines or an inert substance known as a placebo. Neither the scientists conducting the study nor the subjects knew which individuals received the two vaccines or which received the placebo. In such a double-blind study, only once the trial is complete and scientists are ready to analyze its results do they "break the code" to determine the effects of the vaccine.

children received two doses of vaccine (or a placebo) which were given two to three months apart. Two acellular vaccines were used in the study, both produced in Japan. The two vaccines differ in that one is composed of equal parts of two pertussis antigens, while the other contains only one of the antigens. The double component product is one of the approximately six different accellular vaccines that the Japanese government has approved for use in its mass immunization program.[10] The single component vaccine is not, to the best of our knowledge, approved for general use in Japan at this time.

Data concerning adverse reactions which were reported in the children participating in the study, including the deaths of four of the children, are currently being evaluated. The deaths took place between two weeks and five months following the final injection of vaccine, and each was caused by or associated with a severe bacterial infection. Researchers broke the study codes, and it was determined that three of the children had received the two-component Japanese-approved vaccine. The fourth child was in the group that received the new single component product. Any deaths occurring in a study population this small are, of course, taken very seriously. Investigators do not yet know whether these deaths are related to the vaccines in any way and they are exploring that possibility.

The formal analysis of the data amassed in this study —the first controlled efficacy study on any of the new acellular pertussis vaccines—will begin in November, with the final report of the findings expected in mid-1988. The Japanese put their acellular vaccines into widespread use in the absence of a controlled study demonstrating that each of the vaccines was effective in

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[10] Each of these vaccines is composed of different antigens in different ratios to each other. Each product is thus distinct and may have different safety and efficacy characteristics.

preventing pertussis. Thus, the impact of these acellular vaccines on the incidence of the disease in Japan is difficult to evaluate according to some observers. The acellular vaccines appear to be associated with fewer mild local and systemic reactions than the "whole cell" vaccine, and few of the rare and very serious adverse events (such as that alleged by the plaintiff in this case) have been reported to the Japanese government's vaccine compensation system. "Acellular and Whole Cell Pertussis Vaccines in Japan," *Journal of the American Medical Association* ("JAMA") March 13, 1987, 1351-56. Passive reporting systems, which rely on individuals to bring adverse reactions to the attention of public authorities, are not a reliable indicator of the real incidence of adverse reactions, however. The Swedish clinical trial is expected to provide the first scientifically solid proof of whether the acellular vaccines are actually effective in preventing the disease. This study is too small, however, to provide any information concerning rare serious adverse reactions. Thus, even once the Swedish study has been completed, it will take additional time to accumulate such safety data.[11]

The plaintiff argues that because there already existed two types of pertussis vaccine (extracted and acellular) that were as effective as and safer than the "whole cell" vaccine, Lederle could easily have developed one of the

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[11] In addition, significant technical problems must be resolved before an acellular pertussis vaccine can be licensed for use in this country. Indeed, the last day of an international symposium on the development of acellular vaccines sponsored by the Department of Health and Human Services last year was devoted to these issues. They include, among many others, the optimal size and number of doses of the acellular vaccine necessary to confer immunity, the relevance of the Japanese experience (where children are vaccinated at age two years) to the United States (where infants begin receiving pertussis immunization at age two months), and the design of laboratory tests for the vaccine that will demonstrate clinical effectiveness.

other types of vaccine and licensed it for sale. See Brief For Plaintiff-Appellant at 4 and n.4. As the discussion above demonstrates, the state of the scientific knowledge concerning the safety and efficacy of the new types of pertussis vaccines is by no means so clearly settled.

In sum, based on their evaluation of the available scientific and medical evidence, HHS's public health experts have concluded that alternative pertussis vaccines have not yet been adequately shown to be safe and effective for licensure in the United States.

4. *The Federal Role.*

In addition to FDA's role in the licensing and control testing of pertussis vaccines and in the conduct of research concerning the disease, the federal government is actively involved in soliciting and disseminating the views of outside experts on immunization policy, in directly administering federal immunization programs and assisting state programs throughout the country, and in purchasing substantial quantities of vaccine to create a federal stockpile for emergency use.

In the 1960s, the Public Health Service formed the Advisory Committee on Immunization Practices (ACIP), a body of medical specialists which is a prime source of expertise on vaccine issues. Periodically, the ACIP convenes to review vaccines and immunization practices and to make recommendations to public and private health care deliverers. Since its inception, the ACIP has consistently recommended the use of the currently-licensed "whole cell" pertussis vaccine. MMWR, July 12, 1985, p. 2. In reaching its recommendations, the ACIP reviewed the available data concerning the risks of the disease and the pertussis vaccine. The ACIP determined that the risks of rare, severe adverse reactions, including permanent brain damage, temporally associated with the administration of the vaccine were outweighed by the

severe clinical course of the disease (for example, well over half of the infants with pertussis have required hospitalization), the seriousness of the possible complications and permanent consequences, and the infant fatality rate. *Id.* Specifically aware of the possibility of rare, serious adverse reactions associated with the "whole cell" vaccine, the ACIP has concluded, nonetheless, that vaccination against pertussis with this vaccine early in life is essential. The American Academy of Pediatrics, through its Committee on Infectious Diseases, also officially supports this conclusion regarding the importance of immunization with the "whole cell" pertussis vaccine. The Red Book, p. 266-275.

The ACIP has identified certain children who should not receive pertussis vaccine for specific medical reasons and has identified possible adverse reactions and symptoms that contraindicate further immunization with the pertussis vaccine. MMWR, July 12, 1985, p. 7. Lederle's physician labeling includes all warnings recommended by the ACIP.

The ACIP's recommendations appear in the *Morbidity and Mortality Weekly Report* (MMWR), the major information publication of the CDC, which is widely distributed to state and local public health officials and to physicians in private practice and academia. In addition to the publication of the ACIP's views, CDC provides technical assistance concerning immunization, including pertussis immunization, to state and local health departments through a network of regional medical epidemiologists and public health advisors. These CDC representatives are assigned to each state and to some major metropolitan areas, and they participate in their respective states' immunization programs by providing educational information, clarifying the ACIP's recommendations, and helping to ensure an adequate supply of vaccines.

CDC is also a major purchaser of DTP vaccine. In order to achieve the maximum economies of scale and thereby minimize the impact of significant recent increases in the price of the vaccine, CDC last year made a consolidated federal purchase of the vaccine for use by state public health programs.[12] This vaccine is then available at a reduced price to the state health departments for distribution in local public health clinics. The funds for this purchase are authorized under the Immunization Grant Program, formerly known as the Vaccination Assistance Act of 1962, 42 U.S.C. § 247b.[13] The CDC has developed an "Important Information Statement", based on the ACIP recommendations, which discusses the risks and benefits of the "whole cell" vaccine and which must be provided to vaccinees and/or their parents before any vaccine purchased through the federal program is administered. This statement is made freely available to state officials by CDC, and state officials then distribute the statement to their clinics and to private physicians on request. It is believed that the statement is used by many physicians in private practice to inform parents of the benefits and risks associated with immunization with the pertussis vaccine.

In addition to the consolidated federal purchase, the CDC has ordered large quantities of the vaccine in an effort to build a federal stockpile that would represent approximately a six months' supply (four million doses). The stockpiling efforts were undertaken in response to

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[12] The CDC makes its decision from who to purchase its DTP supply solely on the basis of cost, since CDC is convinced that the three licensed manufacturers of DTP vaccine in this country produce equally acceptable, safe, and effective products. During the 12-month period ending in April 1987, CDC purchased nine million doses of the vaccine as part of this program.

[13] Virginia receives grants under this program and is served by a CDC representative in the state who coordinates state and local programs.

a shortage in the supply of the vaccine that occurred in 1984 when there were vaccine production problems and when two of the three licensed manufacturers stopped selling the vaccine for about six months (reportedly due to the manufacturers' inability to arrange for acceptable liability insurance coverage). The supply of DTP in 1983, which was adequate to meet the country's need, was approximately 18.2 million doses, which decreased to 15.6 million in 1984. As a result of the shortage, it was necessary for the ACIP to recommend a change in the immunization schedule, postponing the final two doses of the series of five needed for complete protection. The vaccine shortage recently experienced was a serious public health concern but its impact would appear mild in comparison with the effects of a larger and longer-lasting shortage.[14]

While the government supports the current use of the "whole cell" vaccine, various federal public health agencies are actively involved in pertussis-related research aimed at developing new types of vaccines which may be associated with fewer severe reactions. Government agencies such as NIH, CDC, and FDA are conducting studies in their own laboratories on various aspects of the disease and on new vaccines. These agencies also support research on pertussis in the private sector through grants and contracts.

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[14] The CDC reports that in 1986 there was another shortage of DTP vaccine in the United States. This shortfall was not as serious as that experienced in 1984, but in order to insure that all state and local health departments had an adequate amount of the vaccine, the CDC distributed between 800,000 to 900,000 doses of the one million doses of DTP then in its stockpile. Because of this shortfall and because the manufacturers are producing the vaccine at the limit of their current capacity, it will take longer than expected to accumulate an adequate federal stockpile of the vaccine. In the opinion of the responsible agencies of the U.S. Public Health Service, the regular supply of DTP vaccine has been marginal at best for the last ten years, and a federal stockpile is therefore viewed as extremely important.

The possibility that a vitally important vaccine may be denied to the public before a better alternative becomes available remains of great significance to the public health community. This concern is heightened when the current vaccine has been licensed by the FDA and when its use is strongly recommended by the Public Health Service.

CONCLUSION

The United States presents the foregoing information to this Court.

Respectfully submitted,

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AUGUST 1987

APPENDIX I

42 U.S.C. § 247b Project grants for preventive health services

Grant authority

(a) The Secretary may make grants to States, and in consultation with State health authorities, to political subdivisions of States and to other public entities to assist them in meeting the costs of establishing and maintaining preventive health service programs.

* * * *

(j) Authorization of appropriations

(1)(A) Except for grants for immunization programs the authorization of appropriations for which are established in subparagraph (B), for grants under subsections (a) and (k)(1) of this section for preventive health service programs to immunize without charge individuals against vaccine-preventable diseases, there are authorized to be appropriated $94,000,000 for fiscal year 1988, and such sums as may be necessary for each of the fiscal years 1989 and 1990. Not more than 10 percent of the total amount appropriated under the preceding sentence for any fiscal year shall be available for grants under subsection (k)(1) of this section for such fiscal year.

(B) For grants under subsection (a) of this section for preventive health service programs for the provision without charge of immunizations with vaccines approved for use, and recommended for routine use, after December 1, 1987, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 1988, 1989, and 1990.

* * * *

APPENDIX J

EXCERPT FROM RESPONDENT'S RESPONSE TO DEFENDANT'S SUPPLEMENTAL MEMORANDUM IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT

* * * *

D. SPECIFIC INDICATIONS OF THE INADEQUACY OF DEFENDANT'S WARNING

Defendant could have done so much more to make their warnings fall within the definition of adequate . . . . Given reasonable opportunity, plaintiff can produce affidavits to establish a long list of information available to this defendant which it did not convey in the form of warnings or advice. Included in this list are the following

* * * *

> That there were different formulations for a less-than-whole-cell vaccine described in the literature for many years, which formulations made the pertussis vaccine less reactogenic.

* * * *

APPENDIX K

UNITED STATES COURT OF APPEALS
FIFTH CIRCUIT

No. 87-2578

JAMES L. HURLEY, JR., ETC., *et al.*,
Plaintiffs-Appellants,

v.

LEDERLE LABORATORIES DIVISION OF
AMERICAN CYANAMID CO., *et al.*,
Defendants-Appellees.

Aug. 17, 1988

Appeal from the United States District Court for the Eastern District of Texas.

Before WISDOM, REAVLEY and JOLLY, Circuit Judges.

E. GRADY JOLLY, Circuit Judge:

James Hurley III and his parents appeal the district court's partial summary judgment against their products liability claims arising from the severe neurological damage the minor Hurley sustained after innoculation with Lederle's pertussis (whooping cough) vaccine, 651 F. Supp. 993. Since we disagree with the district court that federal law preempts the state products liability law, and since our examination of the record reveals factual questions remaining on the other issues, we reverse and remand.

I

James Hurley III was less than a year old when he was vaccinated with a DPT vaccine, which includes three separate components to immunize against diptheria, pertussis, and tetanus. The vaccination was done with a "whole cell" pertussis component [1] manufactured by Lederle Laboratories. The child received the vaccine in the office of his personal doctor. Shortly after vaccination, the child sustained severe and irreversible neurological damage. Although Lederle included a warning in its package, this warning was never communicated to the parents. The doctor testified that the warning was adequate to apprise him of the risks inherent in the vaccine. The warning stated:

> ADVERSE REACTIONS
>
> . . . .
>
> Neurological disorders such as encephalopathy possibly due to the pertussis component have been reported to occur rarely following the injection of this product and they may be fatal or result in permanent damage to the central nervous system.
>
> . . . .
>
> Routine immunization should be postponed or avoided in patients with acute infections or a personal or family history of neurological disturbances.

James Hurley III and his parents ("Hurley") brought this diversity action, basing their claims on the Texas law of negligence (alleging a failure to warn adequately

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[1] The diptheria and tetanus components are "toxoids": bacterial toxins artificially modified to eliminate their disease-causing potential. These virtually never cause serious adverse reactions. The pertussis component of the defendant's DPT vaccine, however, is a "whole cell" vaccine: it contains, in an inactive state, all of the components of the pertussis cell. Adverse reactions to this component are more common.

and a failure to design the product properly), warranty (alleging breach of an express and implied warranty that the product would not injure the user in normal use), and strict products liability (alleging the production and marketing of an unreasonably dangerous product). The Hurleys maintain that the drug was unreasonably dangerous because there are alternatives to the "whole cell" pertussis vaccine currently in use in Europe and Japan. The plaintiffs contends that studies of these alternative vaccines show that they are as effective as the "whole cell" vaccine but less likely to cause the type of neurological damage sustained by their child. Although an FDA-approved vaccine similar to those alternatives was sold in the United States from 1962 to 1977, the manufacturer withdrew from the entire vaccine market and none is currently licensed by the FDA for use in the United States.

The plaintiffs also seek punitive damages under Texas law, alleging that the defendants recklessly, knowingly, and willfully failed to warn adequately of possibly severe adverse reactions to their product and to rectify the product's dangerous design.

Lederle maintains that the Hurleys' claims are preempted by federal laws that promote widespread vaccination. Lederle also argues that its warning was adequate, and that the learned intermediary doctrine applies, so that once it had warned Dr. Lanier, it had satisfied its duty.

II

The district court granted partial summary judgment in favor of the defendant, holding that federal laws, such as the Federal Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.*, and the Public Health Act ("PHSA"), 42 U.S.C. §§ 247b and 262, and their attendant regulations, preempted any state law claims based on the inadequacy of Lederle's DPT product warn-

ing as well as any claims based on Lederle's defective design of the DPT vaccine. Moreover, the district court held under the Texas "learned intermediary" doctrine that the manufacturer had a duty to warn the prescribing physician only, rather than the patient or his parents. The district court also held that Lederle's product warning was adequate "as a matter of law" because the prescribing physician, Dr. Lanier, testified that he found it adequate. The plaintiff appeals.

III

A.

Hurley first challenges the district court's decision that federal law preempts his state law tort claims. The concept of preemption has its roots in the supremacy clause: "The Constitution, and the law of the United States which shall be made in Pursuance thereof . . . shall be the supreme law of the Land . . . ." United States Const. art. VI. There are basically two types of preemption, express and implied. *Hillsborough County v. Medical Laboratories, Inc.*, 471 U.S. 707, 712-14, 105 S.Ct. 2871, 2874-76, 85 L.Ed.2d 714 (1985). Lederle's argument and the district court's ruling are based on the contention that, without relief from state law products liability for the pertussis vaccine, manufacturers of the whole cell vaccine will raise prices substantially or withdraw from the market. Thus, Lederle argues and the district court ruled, preemption of state law products liability is implied by the federal scheme to encourage vaccination.

Although the district court arrived at its holding after careful and thoughtful consideration, we must conclude that its holding is flawed. To date, the great majority of United States district courts which have addressed this issue have ruled against preemption.[2] Significantly,

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[2] The following district court opinions have found against preemption: *Smith v. Wyeth Laboratories, Inc.*, No. CA-84-2002, slip

the judge who wrote the original opinion in *Morris v. Parke-Davis & Co.*, which found preemption, and upon which the district court in this case relied, subsequently withdrew and reversed his opinion to find no preemption in the light of the Supreme Court's analysis in *Hillsborough County v. Automated Medical Laboratories, Inc.*, 471 U.S. 707, 105 S.Ct. 2371, 85 L.Ed.2d 714 (1985). *Hillsborough* concerned the preemptive effects of laws of the same types as those in issue here: FDA testing and approval of medical products.

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op. (S.D.W.Va. Aug. 1986); *Milam v. Lederle Laboratories Division of American Cyanamid Co.*, No. CA-4-85-92-K, slip op. (N.D.Tex. Oct. 15, 1986); *Jeski v. Connaught Laboratories, Inc.*, No. A-84-CA-395, slip op. (W.D. Tex. Dec. 18, 1986); *MacGillivray v. Lederle Laboratories Division of American Cyanamid Co.*, 667 F. Supp. 743 (N.D.N.M. 1987); *Morris v. Parke-Davis & Co.*, 667 F. Supp. 1332 (C.D.Cal. 1987); *Knudsen v. Connaught Laboratories*, No. 85-703-Civ.-J-16, slip op. (M.D. Fla. July 31, 1987); *Martinkovic v. Wyeth Laboratories*, 669 F. Supp. 212 (N.D.Ill. 1987); *Koehler v. Wyeth Laboratories*, No. 85-284-C (S.D.Ind. Sept. 8, 1987); *Scholl v. Lederle Laboratories and Connaught Laboratories, Inc.*, —— F. Supp. ——, No. Civ. 85-409-TUC-RMB, slip op. (D. Ariz. Nov. 25, 1987); *Percival v. American Cyanamid Co., d/b/a Lederle Laboratories*, No. Civ. 85-2671-P, slip op. (D. Okla. Nov. 25, 1987) [available on WESTLAW, 1987 WL 46954]; *Patten v. Lederle Laboratories*, 655 F. Supp. 745 (D. Utah 1987); *Wack v. Lederle Laboratories*, 666 F. Supp. 123 (N.D. Ohio 1987); *Graham v. Wyeth Laboratories*, 666 F. Supp. 1482 (D. Kan. 1987); *Foyle v. Lederle Laboratories*, 674 F. Supp. 530 (E.D.N.C. 1987).

Several state courts have also found no federal preemption: *Shepherd v. Lederle Laboratories*, No. 85-20330 (Cr.Ct. Broward County, Fla., Feb. 3, 1988); *Duncan v. Connaught Laboratories, Inc.*, No. 86-CVS888 (Sup. Ct. Columbus County, N.C., March 24, 1988); *Reed v. Connaught Laboratories*, 1426 Civil of 1985, (Court of Common Pleas, Monroe Co., Pa., Dec. 3, 1987).

Although the district court in *Abbott v. American Cyanamid*, No. 86-0857-A, mem. op., (E.D. Va. March 9, 1987), ruled that federal law preempted state tort remedies for DPT vaccination injuries, the Fourth Circuit recently reversed that decision, using reasoning which closely resembles our own. 844 F.2d 1108 (1988).

[1] As a matter of law, the district court's grounds for announcing such a rule cannot survive analysis. Although, as we shall later see, there are some instances in which state law may conflict with individual federal laws or regulations, Lederle's arguments and the district court's holding are so broadly phrased as to preempt all of state products liability law for the manufacture and distribution of the pertussis vaccine. Neither the Food, Drug and Cosmetics Act nor the Public Health Service Act *explicitly* preempts state law. Courts should be reluctant to find that federal law *implicitly* preempts state law. *Hillsborough*, 471 U.S. at 714, 105 S.Ct. at 2375. They may do so only "where the scheme of federal regulation is sufficiently comprehensive to make reasonable the inference that Congress 'left no room' for supplementary state regulation" or "where the field is one in which 'the federal interest is so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject." *Id.* at 713, 105 S.Ct. at 2374.[3] FDA regulation does not generally preempt stricter state law standards for medical products. *Id.* at 717-22, 105 S.Ct. at 2377-80. Moreover, this and other federal courts have already ruled that FDA regulation does not preempt the types of state law duties which are the basis of the plaintiffs' claims: the duty to warn of product risks, *e.g. Osburn v. Anchor Laboratories, Inc.*, 825 F.2d 908, 911-12 (5th Cir. 1987), and the duty not to place unreasonably dangerous products into commerce. *See, e.g.*, district court cases discussed in note 2 above. It is true in theory that a policy-maker could rationally decide to relieve pertussis vaccine manufacturers of lia-

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[3] Even where Congress has not completely displaced state regulations, specific state laws will be preempted (1) when simultaneous compliance with the requirements of federal and state law is impossible, or (2) when compliance with state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Id.* at 713, 105 S.Ct. at 2375.

bility for products defects to ensure a reliable supply of the vaccine or to lower its cost. Nonetheless, because the absence of products liability may discourage vaccine use by increasing quality uncertainty and forcing users to bear the cost of any adverse reaction to vaccination, the ultimate effect on vaccination levels is too uncertain for a court to intrude into what is essentially a policy question. Moreover, it is not clear that the cost of compensating children injured by the vaccine would drive vaccine manufacturers from the business; the manufacturers may be able to raise prices and preserve their profit margin. Because the vaccine price is paid by the federal government, this would make the vaccination program a greater burden on the federal fisc, but it would not discourage parents from having their children vaccinated. Accordingly, the decision to preempt state law products liability would be a difficult one for a policy-maker and it is not appropriate for us to assume that decision has been made based on such inconclusive evidence.

Lederle argues that, because the FDA has not approved marketing of any alternative to the whole-cell vaccine, "the scheme of federal regulation" in this case is to encourage vaccination with the whole-cell vaccine in particular. We cannot accept this assumption because the FDA is a passive agency: it considers whether to approve vaccine designs only if and when manufacturers come forward with a proposal. *See Osburn*, 825 F.2d at 912. Thus, the absence of FDA-approved alternatives to whole-cell vaccine does not indicate FDA disapproval of any such alternative. There is no basis for finding a federal interest in a particular form of the pertussis vaccine.

Lederle also argues that the Public Health Service Act and its attendant regulations represent a pervassive federal scheme, and as such, preempt state law products liability for vaccine manufacturers. As Justice Marshall explains in *Hillsborough*, this argument is over inclusive:

> As a result of their specialized functions, agencies normally deal with problems in far more detail than does Congress. To infer preemption whenever an agency deals with a problem comprehensively is virtually tantamount to saying that whenever a federal agency decides to step into a field, its regulations will be exclusive.

105 S.Ct. at 2377. Thus, the Supreme Court has hesitated to infer such preemption. For example, in *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 288, 104 S.Ct. 615, 78 L.Ed.2d 443 (1984), the Supreme Court found that the highly regulated scheme established by the Atomic Energy Act of 1954 did not implicitly preempt state tort law liability for nuclear power plant accidents. If the comprehensive and intricate plan of AEA regulation does not implicitly preempt state tort law by taking over the entire field, there is no reason to think that Congress intended the PHS vaccination program it approved in 1962, however "aggressive" it might be, to include—by implication—a holiday from state products liability law for vaccine manufacturers.

Finally, we believe that any case for preemption is doomed by the National Childhood Vaccine Injury ["NCVI"] Act of 1986, 42 U.S.C. §§ 300aa-33. Although the NCVI Act was passed after this case was filed, it is relevant as proof that Congress intends no preemption of the state law liability of vaccine manufacturers. The NCVI Act clearly states that state law remedies apply to the manufacture and sale of vaccines and it even makes recovery easier for injured consumers.

In sum, it is possible to construct sound policy arguments in favor of preemption in this case, but there is virtually no indication in the relevant law that Congress or the FDA explicitly or implicitly accepted them.

B.

[2] Next we consider whether the doctrine of the learned intermediary applies in this case. This doctrine applies when a patient receives a drug or vaccination through a doctor who weighs the risks and benefits, and makes the decision to administer it. In such a case, the fact that the manufacturer has adequately warned the prescribing physician will protect it from liability to the patient for failure to warn. *Reyes v. Wyeth Laboratories*, 498 F.2d 1264 (5th Cir.1974). Although the district court considered this doctrine, it did not analyze whether the "mass immunization" exception to that doctrine applies. We therefore turn to examine that question now. This exception becomes applicable when vaccines are used in mass immunization programs "where no individualized medical judgment intervenes between the manufacturer . . . and the ultimate consumer. . . . [In such a case], it is the responsibility of the manufacturer to see that the warnings reach the *consumer*, either by giving the warning itself, or by obligating the purchaser to give the warning." *Id.* at 1276. Several issues concerning this question will be evident to the district court on remand. First, the learned intermediary doctrine relates only to the issue of whom the manufacturer warned. It does not govern the adequacy of the warning. The doctrine, if it applies, will foreclose any question whether the manufacturer warned the proper party, since it is settled that the manufacturer did provide a warning in the package it sent to Dr. Lanier. Even assuming that it does apply, however, the question remains whether the warning adequately apprised Dr. Lanier of the risks attending the DPT vaccine. (Dr. Lanier testified that he considered the warning adequate, but his testimony does not dispose of the question. Although his testimony is competent on the issue, the adequacy of the warning is not a matter that can be conclusively resolved solely on the basis of the administering

physician's opinion.) If the learned intermediary doctrine does not apply, the general rule applies that the ultimate consumer must be warned, in this case the parents of James Hurley III.

[3] On the record as it now stands, it seems quite possible that the learned intermediary doctrine will apply, since James Hurley III received the vaccine in the office of his own personal physician. We must remand this issue, however, because some questions of fact remain as to the circumstances surrounding James' vaccination. The plaintiffs contend that it took place in a "clinic-like" atmosphere, wherein a nurse administered the vaccine as a routine matter, and the prescribing physician never saw the patient at all and, in fact, was not even in the office. The record, however, does not reflect whether Dr. Lanier was familiar with the patient or had other contact with him. As we recently observed in *Osburn v. Anchor Laboratories, Inc.*: "[T]he rationale underlying the learned intermediary doctrine is that by virtue of his medical expertise, a physician has knowledge not only of the dangerous propensities of drugs, but also of the particular 'susceptiblities of his patient[s].'" 825 F.2d 908, 913 (5th Cir.1987) (quoting *Reyes*, 498 F.2d at 1276). Thus, the question of fact remains, whether Dr. Lanier made a professional judgment about the safety and usefulness of the DPT vaccine for James Hurley III, or whether the immunization procedure was more like that of a clinic in which no doctor was involved in administering the drug.

[4] We do not agree, and we do not believe that the Texas courts would agree that the manufacturer must warn *all* ultimate consumers of the vaccine regardless of the setting in which they receive the vaccine simply because the vaccine is sometimes used in a mass immunization setting. *See, e.g., Williams v. Lederle Laboratories*, 591 F.Supp. 381 (S.D.Ohio 1984). The learned intermediary doctrine is the rule, and the mass immuni-

zation case is the exception. We believe that the rule should stand whenever a physician has made a professional judgment, and that the mass immunization exception should apply only when no informed medical decision came between the manufacturer and the ultimate user. The case law indicates that if no such judgment has intervened, the user may sue the manufacturer for failure to provide him or her with a warning, even though the manufacturer may reasonably have assumed that a professional judgment *would* have intervened as in a case where it had sold the vaccine to a private physician. "[W]here no individualized medical judgment intervenes between the manufacturer . . . and the ultimate consumer, it is the responsibility of the manufacturer to see that the warnings reach the *consumer*. . . ." *Reyes*, 498 F.2d at 1276. In sum, a manufacturer will be liable to the ultimate user of its drug or vaccine product unless it provided that user with an adequate warning, *or* an informed professional judgment actually intervened in the application of the product to that user.

C.

The next question we must address concerns the adequacy of the warning Dr. Lanier received. Once again, if the district court were to decide that the learned intermediary doctrine does not apply, the question of the adequacy of this warning may ultimately be moot because it was not given to the proper party. In case the learned intermediary doctrine does apply, we turn now to consider the issues that will be before the district court on the adequacy of the warning.

[5] The defendants propose that the question of adequacy of the warning is preempted by federal law since the warning used was FDA approved. The preemption they suggest is implied preemption; in essence, they argue that state law would impermissibly conflict with federal law if it required a warning different from that

approved and required by the FDA. This is the one question in this case for which the defendants' arguments on preemption are compelling; however, they are not airtight. In the area of approving warnings, although the FDA takes an active role in designing the warning, it remains a partially passive agency. That is, it accepts information given by manufacturers proposing the licensing of a particular vaccine, and determines a proper warning based upon the information provided. 21 C.F.R. §§ 601.2, 601.12, 601.25. A state law determination on this issue should not be interjected to overrule the decision of the FDA. Such a procedure would place vaccine manufacturers in a position where they could not comply with both obligations. The FDA extensively regulates the contents and wording of these product inserts. *See, e.g.*, 21 C.F.R. §§ 1 and 201; 50 Fed.Reg. 51.108 (1985). A manufacturer must first provide all the relevant information to the FDA, which then determines a warning it deems appropriate. The manufacturer is required to print that precise warning in its product insert. *Id.* Most important, the manufacturers cannot change the language in the product insert without FDA approval. 21 C.F.R. § 601.12. It would be patently inconsistent for a state then to hold the manufacturer liable for including that precise warning when the manufacturer would otherwise be liable for *not* including it. Thus, assuming that the FDA has processed all the relevant and available information in arriving at the prescribed warning, its decision as to the proper wording must preempt by implication that of a state. Specifically, such a case would fit one of the scenarios described in *KVUE, Inc. v. Austin Broadcasting Corp.* as indicating preemption: "the state statute actually and directly conflicts with federal law." 709 F.2d 922, 931-32 (5th Cir. 1983).

[6] A factual issue remains, however, as to whether the manufacturer provided the FDA all the necessary and

available information on which to base the warning. Thus, the only question that can be presented to the jury consistent with the federal regulatory scheme is whether the manufacturer withheld, either at the time the FDA decided the content of the warning, or since then, information that would have changed the FDA's decision. We believe that this issue should be presented to the jury in the form of special interrogatories, questioning whether and what information the manufacturer withheld from the FDA, if any, and whether possession of this information would have materially altered the content of the FDA's warning. This special procedure is justified by the federal interest in encouraging manufacturers to produce vaccines, in that those manufacturers need some assurance that if they follow certain prescribed procedures, such as including an FDA-approved warning, they are complying with the law.

D.

Finally, we note that the learned intermediary doctrine applies only to the inadequate warning claims; it does not address design defects. *Abbot v. American Cyanamid*, 844 F.2d 1108 (4th Cir.1988). The district court dealt with the design defect issues only under its discussion of preemption. Since we have held that preemption does not apply in this case, we must remand the design defect claims to the district court.[4]

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[4] Although it would seem likely, we leave it to the district court to consider whether a parallel analysis to that applied in the warning context should apply to design-defect claims. That is, although FDA regulation has not preempted the entire field of design defect, assuming that the FDA processed all necessary and available data, does FDA approval preempt a claim that the product in design is unreasonably dangerous? We do not decide this question since we do not have the benefit of a district court's reasoning on it. We wish to make clear, however, that our holding against general preemption does not necessarily exclude the possibility of such a specific preemption.

IV

In conclusion, we hold that federal law does not preempt state products liability law governing vaccinations. We therefore remand the Hurleys' claims to the district court for further consideration. The record is insufficient for us to determine whether the learned intermediary doctrine applies. With respect to the adequacy of the warning, the record is insufficient, since the adequacy of the warning must be determined in the light of whether Lederle withheld material information from the FDA. Otherwise, the FDA-approved warning is sufficient. Finally, the district court dealt with the remaining claims only under its preemption analysis. Since we have concluded that state product-liability law is not preempted, we remand for further proceedings not inconsistent with this opinion.

REVERSED AND REMANDED.